**Index of Attachments for Petition for Postponement of "Strengthening Transparency" Rule, 86 Fed Reg. 469 (Jan. 6, 2021) Pursuant to 5 U.S.C. § 705**

**Docket ID No. EPA-HQ-OA-2018-0259**

*Submitted via email*

*January 28, 2021*

## Index of Attachments

Attachment A: *Envtl. Def. Fund v. EPA*, No. 4:21-cv-03 (D. Mont. Jan. 27, 2021).

Attachment B: Letter from Ninety Members of the U.S. House of Representatives to President Joseph R. Biden, Jr. (Jan. 27, 2021).

Attachment C: Briefing: Data Transparency, Administrator's Office (Jan. 25, 2017). [EPA has informed EDF that this document was misdated and should have read "January 25, 2018."]

Attachment D: Thomas Sinks, Differing Scientific Opinion on the Final Strengthening Transparency in Regulatory Science Rule.

Attachment E: Birnbaum Decl. in *Envtl. Def. Fund v. EPA*, No. 4:21-cv-03 (D. Mont. Jan. 27, 2021).

Attachment F: Sarnat Decl. in *Envtl. Def. Fund v. EPA*, No. 4:21-cv-03 (D. Mont. Jan. 27, 2021).

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Attachment H: Balmes Decl. in *Envtl. Def. Fund v. EPA*, No. 4:21-cv-03 (D. Mont. Jan. 27, 2021).

Attachment I: Karagas Decl. in *Envtl. Def. Fund v. EPA*, No. 4:21-cv-03 (D. Mont. Jan. 27, 2021).

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Attachment K: Stith Decl. in *Envtl. Def. Fund v. EPA*, No. 4:21-cv-03 (D. Mont. Jan. 27, 2021).

Attachment L: McPartland Decl. in *Envtl. Def. Fund v. EPA*, No. 4:21-cv-03 (D. Mont. Jan. 27, 2021).

Attachment M: Liebert Decl. in *Envtl. Def. Fund v. EPA*, No. 4:21-cv-03 (D. Mont. Jan. 27, 2021).

**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF MONTANA**
**GREAT FALLS DIVISION**

ENVIRONMENTAL DEFENSE FUND; MONTANA ENVIRONMENTAL INFORMATION CENTER; and CITIZENS FOR CLEAN ENERGY,

Plaintiffs,

vs.

U.S. ENVIRONMENTAL PROTECTION AGENCY; and ANDREW R. WHEELER, in his official capacity as Administrator of the U.S. Environmental Protection Agency,

Defendants.

**4:21-cv-03-BMM**

**ORDER**

## INTRODUCTION

Environmental Defense Fund ("EDF"), Montana Environmental Information Center ("MEIC"), and Citizens for Clean Energy ("CCE") (collectively, "Plaintiffs") brought this action against the U.S. Environmental Protection Agency ("EPA") and Andrew R. Wheeler in his official capacity as Administrator of EPA ("Federal Defendants") to challenge an EPA rulemaking. (Doc. 1). Plaintiffs allege two counts: that the final rule itself was unlawful; and that EPA's decision to make the final rule effective on publication was unlawful. (Doc. 1 at 10–13).

Plaintiffs filed a Motion to Expedite their Motion for Partial Summary Judgment. (Doc. 7). Plaintiffs also filed concurrently a Motion for Partial Summary Judgment centered on the effective date count. (Doc. 8). Plaintiffs seek an order declaring unlawful and setting aside EPA's decision to make the final rule effective immediately and declaring that the final rule should remain ineffective until 30 days from its publication date. (Doc. 8 at 1–2; Doc. 9 at 3–4).

Plaintiffs proposed an expedited briefing schedule for their summary judgment motion. (Doc. 7 at 3). Federal Defendants disagreed with the justification for expedited resolution, but asserted they would "nevertheless agree with the briefing schedule set forth" in Plaintiffs' motion. (Doc. 16 at 1). The Court granted the Motion to Expedite. (Doc. 18). The Motion for Partial Summary Judgment proves fully briefed and ripe. (Docs. 8, 9, 24, 27).

## BACKGROUND

### *Factual Background*

President Richard Nixon established EPA in 1970 "to make a coordinated attack on the pollutants which debase the air we breathe, the water we drink, and the land that grows our food." Reorganization Plan No. 3 of 1970 (July 9, 1970). William D. Ruckelshaus, the first EPA Administrator, further elaborated that EPA has a "broad responsibility for research, standard-setting, monitoring and enforcement with regard to five environmental hazards: air and water pollution,

solid waste disposal, radiation, and pesticides." EPA's First Administrator on Establishment of EPA, Press Release (Dec. 16, 1970).

EPA's mission remains "to protect human health and the environment." EPA achieves that mission through the implementation of these core environmental laws: the Clean Air Act ("CAA"), 42 U.S.C. §§ 7401–7671q; the Clean Water Act ("CWA"), 33 U.S.C. §§ 1251–1387; the Safe Drinking Water Act ("SDWA"), 42 U.S.C. §§ 300f–300j-26; the Toxic Substances Control Act ("TSCA"), 15 U.S.C. §§ 2601–2697; the Emergency Planning and Community Right-to-Know Act ("EPCRA"), 42 U.S.C. §§ 11001–11050; and the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. §§ 136–136y, among others.

EPA implements these substantive environmental statutes by establishing quantitative limits and standards to protect public health and the environment. Congress directed EPA through those statutes to use the "latest," "generally accepted," and "best available" science to inform the agency's decisions. For one example, the CAA requires EPA to establish science-based standards to control air pollution to protect public health and welfare. *See* 42 U.S.C. § 7401(b)(1); *Am. Lung Ass'n v. Envtl. Prot. Agency*, No. 19-1140, 2021 WL 162579, at *25–*26 (D.C. Cir. Jan. 19, 2021) (describing the purpose and history of the CAA).

EPA sets air pollution standards known as air quality criteria that must "accurately reflect the latest scientific knowledge." 42 U.S.C. § 7408(a)(2). EPA

must consider "all identifiable effects [of air pollutants] on public health and welfare" and "include information" on certain science-based factors "to the extent practicable" when it establishes air quality criteria. *Id.* EPA must then use these criteria to adopt National Ambient Air Quality Standards ("NAAQS") at levels requisite to protect public health with an adequate margin of safety. *See id.* § 7409(b). The CAA further requires EPA to evaluate health risks and effects of hazardous air pollutants ("HAPs") and to set emission standards to reduce such risks using science-based considerations. *See id.* § 7412. As part of the residual risk requirements, EPA also must investigate and report on "the actual health effects with respect to persons living in the vicinity of sources," and "any available epidemiological or other health studies" regarding the effects of HAPs. *Id.* § 7412(f)(1)(C).

EPA relies on a wide range of scientific research to implement its standards and rules. Such research includes epidemiological studies that use dose-response data to link exposure to a pollutant, contaminant, or substance to a public health or environmental harm. Some of these epidemiological studies—particularly studies that examine small populations or populations with unique health challenges—use data that includes confidential medical or other personally identifiable information. Such information could be used to identify study participants. Federal law generally prohibits public disclosure of these data to protect the privacy of those

who participated in those studies. *See, e.g.*, Health Insurance Portability and Accountability Act ("HIPAA") Privacy Rules, 45 C.F.R. Parts 160 and 164, Subparts A & E (establishing safeguards to protect the privacy of personal health information, and setting limits and conditions on the uses and disclosures that may be made of such information without patient authorization); 21st Century Cures Act, 42 U.S.C. § 241 (requiring government agencies to provide a certificate of confidentiality to protect the privacy of individuals participating in certain research); Privacy Act of 1974, 5 U.S.C. § 552a (precluding disclosure of personally identifiable information or records by government agencies except in very limited enumerated circumstances).

As a result, public health researchers frequently make confidential the data that underlies their findings. The scientific community has developed methodologies, such as peer review, to validate the result of studies even when the underlying data remains unavailable publicly. *See* Jeremy Berg, Philip Campbell, Veronique Kiermer, Natasha Raikhel & Deborah Sweet, *Joint Statement on EPA Proposed Rule and Public Availability of Data*, Nature (Apr. 30, 2018). EPA long has relied on these proven review mechanisms to ensure that the public health studies that underly regulatory decisions prove scientifically valid. The D.C. Circuit previously upheld a challenge to EPA's practice of relying on studies with confidential underlying data. *See Am. Trucking Ass'ns, Inc. v. EPA*, 283 F.3d 355,

372 (D.C. Cir. 2002). The D.C. Circuit concluded, in part, that "requiring agencies to obtain and publicize the data underlying all studies on which they rely" would be "impractical and unnecessary." *Id.*

*EPA Rulemaking*

On April 30, 2018, EPA proposed a rule to "enhanc[e] the transparency and validity of the scientific information relied upon by EPA" in its regulatory decision-making. Strengthening Transparency in Regulatory Science, 83 Fed. Reg. 18,768, 18,768–69 (Apr. 30, 2018) ("First Proposed Rule"). The First Proposed Rule would require EPA to ensure that dose response data and models underlying "pivotal regulatory science" were publicly available for validation and analysis. *See id* at 18,770. EPA defined "pivotal regulatory science" as "studies, models, and analyses that drive the magnitude of the benefit-cost calculation, the level of a standard, or point of departure from which a reference value is calculated." *Id.*

EPA sought to "change agency culture and practices regarding data access" by "exercis[ing] its discretionary authority to establish a policy that would preclude it from using [non-public] data in future regulatory actions." *Id.* at 18,769 n.3. To that end, EPA's First Proposed Rule would preclude the use of scientific studies when making regulatory decisions on the basis that the underlying data were not publicly available. The First Proposed Rule included a provision that would permit

the EPA Administrator to "exempt significant regulatory decisions" from the rule, but it failed to provide a standard to apply that exemption. *Id.* at 18,772.

EPA proposed to promulgate the First Proposed Rule "under the authority of the statutes it administers." *Id.* at 18,768 (citing CAA, 42 U.S.C. §§ 7403, 7601(a); CWA, 33 U.S.C. §§ 1254, 1361; SDWA, 42 U.S.C. §§ 300j-1, 300j-9(a)(1); Resource Conservation and Recovery Act ("RCRA"), 42 U.S.C. §§ 6912(a)(1), 6979; Comprehensive Environmental Response, Compensation, and Liability Act ("CERCLA"), 42 U.S.C. §§ 9616, 9660; EPCRA, 42 U.S.C. § 11048; FIFRA, 7 U.S.C. §§ 136r(a), 136w; and TSCA, 15 U.S.C. § 2609).

EPA extended the comment period for the First Proposed Rule on May 25, 2018. *See* 83 Fed. Reg. 24,255, 24,256 (May 25, 2018). EPA also expanded its claim of authority to promulgate the First Proposed Rule to include the Federal Housekeeping Statute "in addition to the authorities" previously listed. *Id.* The Federal Housekeeping Statute provides "[t]he head of an Executive department or military department" with authority to "prescribe regulations for the government of his [or her] department, the conduct of its employees, the distribution and performance of its business, and the custody, use, and preservation of its records, papers, and property." 5 U.S.C. § 301; *see also Chrysler Corp. v. Brown*, 441 U.S. 281, 310 (1979) (describing the statute as "simply a grant of authority to the agency to regulate its own affairs").

On March 18, 2020, EPA issued a Supplemental Notice of Proposed Rulemaking "to clarify, modify and supplement certain provisions" in the First Proposed Rule. 85 Fed. Reg. 15,396, 15,398 (Mar. 18, 2020) ("Second Proposed Rule"). The Second Proposed Rule expanded the initial proposal in two ways. The Second Proposed Rule would apply to all "data and models, not only dose-response data and dose-response models." *Id.* at 15,398. EPA also sought to apply the rule's constraints to "influential scientific information," rather than only to "significant regulatory decisions." *Id.* The Second Proposed Rule still provided an avenue for the EPA Administrator to grant exemptions from the rule when compliance would be "impracticable," but failed to provide further guidance regarding what would qualify as impracticable. *Id.* at 15,406.

EPA narrowed the statutory justification for the Second Proposed Rule. EPA no longer "propose[d] to interpret provisions of a particular statute or statutes that it administers." *Id.* at 15,398. EPA suggested instead that it retained authority to promulgate the rule from the Federal Housekeeping Statute. *Id.*

The First Proposed Rule and the Second Proposed Rule together drew significant criticism from inside and outside the federal government. The two rules together received nearly one million public comments. Leading scientists at the National Academies of Sciences, Engineering, and Medicine cautioned that the First Proposed Rule "pose[d] a threat to the credibility of regulatory science."

Letter from Marcia McNutt, President, Nat'l Acad. of Sciences, C.D. Mote, Jr., President, Nat'l Acad. of Eng. & Victor J. Dzau, President, Nat'l Acad. of Med., to Andrew Wheeler, Acting Administrator, EPA (July 16, 2018). EPA's own Science Advisory Board ("SAB") submitted comments critical of the Second Proposed Rule. SAB asserted that "[t]here is minimal justification provided in the Proposed Rule for why existing procedures and norms utilized across the U.S. scientific community, including the federal government, are inadequate." Science Advisory Board Consideration of the Scientific and Technical Basis of EPA's Proposed Rule Titled "Strengthening Transparency in Regulatory Science" at 17 (Apr. 24, 2020). SAB concluded that "[s]uch a proposal is inconsistent with the scientific method that requires all credible data be used to understand an issue and to allow systematic review to evaluate past research." *Id.* at 9.

On January 6, 2021, nearly two and a half years after EPA published the First Proposed Rule, EPA published its final rule in the Federal Register. Strengthening Transparency in Pivotal Science Underlying Significant Regulatory Actions and Influential Scientific Information, 86 Fed. Reg. 469 (Jan. 6, 2021) ("Final Rule"). The Final Rule provides that "when promulgating significant regulatory actions or developing influential scientific information, [EPA] will determine which studies constitute pivotal science and give greater consideration to those studies determined to be pivotal science for which the underlying dose-

response data are available in a manner sufficient for independent validation." *Id.* at 470. EPA limited the Final Rule to apply only to dose-response data rather than all underlying data. *Id.* at 474–75. The Final Rule defines "pivotal science" as those studies "that are integral to characterizing dose-response relationships" and that "drive the requirements or quantitative analyses of EPA significant regulatory actions or influential scientific information." *Id.* at 480.

The Final Rule provides two ways that EPA still may consider pivotal science when underlying data was not made public due to technological infeasibility or privacy. *Id.* at 477. In the first, EPA "shall" give that research "lesser consideration." *Id.* In the second, the EPA Administrator may grant a regulation a case-by-case exemption from the Final Rule's application. *See id.* The Final Rule limited the EPA Administrator's discretion to grant exemptions for a limited set of reasons with a written justification. *See id.* The Final Rule further provides that when conflicts arise between it and the requirements of environmental statutes and regulations, the Final Rule limitations "will yield and the statutes and regulations will be controlling." *Id.* at 470.

EPA did not provide guidelines or procedures for how it would implement the Final Rule. For example, EPA did not provide a process for how the agency will undertake the following activities: identify and deal with any conflicts with existing laws; designate key studies as pivotal science; document the availability of

dose-response data; and request and process an EPA Administrator exemption. *See id.* at 471 (noting plans to issue such guidance in the future).

EPA promulgated the Final Rule in reliance on authority derived from the Federal Housekeeping Statute. *Id.* EPA characterized the Final Rule as a procedural rule because it "pertains to the internal practices of the EPA." *Id.* Although acknowledging that EPA is "not one of the 'Executive departments' referred to" in the Federal Housekeeping Statute, EPA argued that it gained housekeeping authority through Section 301 of the Reorganization Plan No. 3 of 1970. *Id.* (citing Reorganization Plan No. 3 of 1970, 84 Stat. 2086 (July 9, 1970)).

EPA declared the Final Rule effective upon publication in the Federal Register on January 6, 2021. *Id.* at 472. EPA provided two justifications for the Final Rule's immediate effect. First, that the Final Rule governs internal EPA procedure, and, therefore, stands exempt from the general 30-day notice requirement of the Administrative Procedure Act ("APA"). *Id.* (citing 5 U.S.C. §§ 553(d)(2)). Second, that EPA found "good cause" to make the Final Rule effective immediately "because immediate implementation . . . is crucial for ensuring confidence in EPA decision-making." *Id.* (citing 5 U.S.C. § 553(d)(3)).

*Legal Standard*

A court should grant summary judgment where the movant demonstrates that no genuine dispute exists "as to any material fact" and the movant is "entitled

to judgment as a matter of law." Fed. R. Civ. P. 56(a). Summary judgment remains appropriate for resolving a challenge to a federal action when review will be based primarily on the administrative record. *Pit River Tribe v. U.S. Forest Serv.*, 469 F.3d 768, 778 (9th Cir. 2006). Under the APA, a reviewing court "shall . . . hold unlawful and set aside" agency action that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A).

## ANALYSIS

### I. Article III Standing

Plaintiffs must establish that they possess standing to invoke the Court's jurisdiction. *See Lujan v. Defs. of Wildlife*, 504 U.S. 555, 559–60 (1992). Standing represents an "indispensable part of [a] plaintiff's case." *Id.* at 561. The "irreducible constitutional minimum of standing" contains three elements: injury-in-fact, causation, and redressability. *Id.* at 560; *see also Summers v. Earth Island Inst.*, 555 U.S. 488, 493 (2009). "The party invoking federal jurisdiction bears the burden of establishing these elements." *Lujan*, 504 U.S. at 561.

Plaintiffs argue that they fulfill the standing requirement based on both organizational and representational standing theories. (Doc. 9 at 28). An organization wields organizational standing if the challenged action frustrates its goals and requires it to expend resources it would have spent in other ways. *See Comite de Jornaleros de Redondo Beach v. City of Redondo Beach*, 657 F.3d 936,

943 (9th Cir. 2011). An organization wields representational standing and may sue on behalf of its members if "(a) its members would otherwise have standing to sue in their own right; (b) the interests it seeks to protect are germane to the organization's purpose; and (c) neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit." *Oklevueha Native Am. Church of Haw., Inc. v. Holder*, 676 F.3d 829, 839 (9th Cir. 2012) (quoting *Hunt v. Wash. State Apple Advert. Comm'n*, 432 U.S. 333, 343 (1977)). Federal Defendants assert that Plaintiffs failed to identify a legally cognizable injury traceable to EPA's decision to issue the Final Rule. (Doc. 24 at 13).

**a. Injury-in-Fact**

To demonstrate injury-in-fact, a plaintiff must show that it suffered "an invasion of a legally protected interest" that is "concrete and particularized" and "actual or imminent, not conjectural or hypothetical." *Spokeo, Inc. v. Robins*, ___ U.S. ___, ___, 136 S. Ct. 1540, 1548 (2016) (quoting *Lujan*, 504 U.S. at 560). In a procedural standing case, a plaintiff must show that the procedures at issue are designed to protect some "threatened concrete interest" to prove an injury-in-fact. *WildEarth Guardians v. U.S. Dep't of Agric.*, 795 F.3d 1148, 1154 (9th Cir. 2015).

**i. Procedural Injury-in-Fact**

Plaintiffs have demonstrated a procedural injury-in-fact. To establish a procedural injury-in-fact, a plaintiff "must demonstrate (1) that [it] has a

procedural right that, if exercised, could have protected [its] concrete interests, (2) that the procedures in question are designed to protect those concrete interests, and (3) that the challenged action's threat to the plaintiff's concrete interests is reasonably probable." *California v. Azar*, 911 F.3d 558, 570 (9th Cir. 2018).

The APA grants Plaintiffs and their members a procedural right to petition to postpone the Final Rule's effective date. Section 705 authorizes an agency to postpone a rule "pending judicial review" as "justice requires." 5 U.S.C. § 705. This process provides a petitioner with immediate relief from a regulation while the courts consider the merits of a legal challenge. The Section 705 process contains a crucial caveat: a rule that is already in effect cannot be "postponed." *Clean Air Council v. Pruitt*, 862 F.3d 1, 9 (D.C. Cir. 2017); *Nat. Res. Def. Council v. Nat'l Highway Traffic Safety Admin.*, 894 F.3d 95, 113 (2d Cir. 2018). Plaintiffs allege that EPA unlawfully made the Final Rule effective on publication. EPA's decision to make the Final Rule immediately effective cut off Plaintiffs' ability to seek postponement under Section 705 as Plaintiffs would have been entitled to do under proper circumstances.

Federal Defendants respond that Plaintiffs "have not lost the opportunity to petition" EPA because other petition avenues remain available under the APA. (Doc. 24 at 16–17). Federal Defendants point to Section 553(e), which gives any "interested person the right to petition for the issuance, amendment, or repeal of a

rule." 5 U.S.C. § 553(e). That argument ignores the distinctions, however, between the different petition remedies Congress made available through the APA. Section 705 can provide a petitioner immediate and preemptive relief from a pending regulation. *Id.* § 705. Section 705 stands available only to those petitioners who are seeking judicial redress. *Id.* Section 705 uniquely forces the agency to consider whether the ends of justice require the agency to delay the effect of a pending rule. *Id.* In comparison, Section 553(e) requires a petitioner to seek rule amendment pursuant to notice-and-comment rulemaking—a process that would take months to complete. *See Riverbend Farms, Inc. v. Madigan,* 958 F.2d 1479, 1484 (9th Cir. 1992). Petitioners would remain subject to the regulation in the interim. Plaintiffs and their members retain the unique procedural right to petition EPA to postpone the Final Rule's effective date under Section 705.

It proves likely that Plaintiffs could have protected their concrete interests if they had been able to use the Section 705 process. "Elections have policy consequences." *Organized Village of Kake v. U.S. Dep't of Agric.*, 795 F.3d 956, 968 (9th Cir. 2015) (en banc); *see also Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 59 (1983) (Rehnquist, J., concurring) ("A change in administration brought about by the people casting their votes is a perfectly reasonable basis for an executive agency's reappraisal of the costs and benefits of its programs and regulations."). The new administration has identified

the Final Rule as a priority for immediate review. *See* Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis, Executive Order 13,990, Sec. 2(a)(iv) (Jan. 20, 2021). At least "some possibility" exists that Plaintiffs could have vindicated their concrete interests through a petition submitted under Section 705. *Massachusetts v. EPA*, 549 U.S. 497, 518 (2007) (requiring "some possibility" that an agency would consider a petition).

Section 705 was designed to protect Plaintiffs' concrete interests. The Section 705 procedure to delay the implementation of a pending rule directly implicates the APA's standard 30-day notice requirement for a substantive rule. The "primary purpose" of the 30-day notice requirement serves "to permit petitions for reconsideration and to afford persons affected a reasonable time to prepare for the effective date of a rule or rules or to take other action which the issuance may prompt." *Nance v. EPA*, 645 F.2d 701, 708–09 (9th Cir. 1981). Such actions include a petition for the agency to delayed implementation under Section 705.

A delay provides immediate, if temporary, relief from a pending rule while a petitioner seeks judicial redress. The APA allows an agency to postpone a rule "pending judicial review" as "justice requires." 5 U.S.C. § 705. Plaintiffs filed the above-captioned challenge to the Final Rule. Plaintiffs stand in the position contemplated by Section 705 and could have petitioned EPA to consider postponement after the agency engages in an "impartial look at the balance struck

between the two sides of the scale, as the iconic statue of the blindfolded goddess of justice holding the scales aloft depicts." *State v. United States Bureau of Land Mgmt.*, 277 F. Supp. 3d 1106, 1122 (N.D. Cal. 2017).

The Final Rule and its immediate effect present a reasonably probable threat to Plaintiffs' concrete financial and professional interests as organizations and through their members. For example, Plaintiffs argue that the Final Rule will harm member-scientists' financial interests because it forces those member-scientists to adapt and restructure current applications for grant funding from the National Institutes of Health ("NIH"). (Doc. 9 at 32–36; Doc. 27 at 15–17) (citing Sarnat Decl. ¶¶ 7, 9–13; J. Lewis Decl. ¶¶ 3, 21, 23, 25–26; Balmes Decl. ¶¶ 15–19). Plaintiffs identify specific scientists and specific grants, including grants with deadlines in February 2021. (Doc. 9 at 32–36; Doc. 27 at 15–17). Plaintiffs further argue that the Final Rule threatens those same scientists' professional interests in pursuing their intended research agendas, working with underserved communities, and informing policymaking by publishing research that will be accorded full weight. (Doc. 9 at 36–38; Doc. 27 at 15–17).

Federal Defendants respond that any alleged threat to Plaintiffs' concrete interests rely on "speculative assumptions," represent "self-inflicted harms," and are "purely voluntary" in nature. (Doc. 24 at 18, 20–21). Plaintiffs' concerns need not be certain to claim standing. They must be *reasonably probable*. *California v.*

*Azar*, 911 F.3d at 570. Plaintiffs meet that burden. Plaintiffs identified specific member-scientists who rely on dose-response data that cannot be made available for independent verification. (Doc. 27 at 16) (citing Sarnat Decl. ¶¶ 7, 9–11; J. Lewis Decl. ¶¶ 21, 23, 25; Balmes Decl. ¶ 16.). Plaintiffs' member-scientists raised reasonable concerns that the NIH will afford their grant proposals less weight due to the potential limited application of their research on regulatory design. *See id.* A former NIH official corroborated those concerns in a declaration. *See id.* (citing Birnbaum Decl. ¶ 13) (noting in her experience that research that is "unlikely or unable to be used to inform EPA decisionmaking" or will receive "limited weight in that decisionmaking" is "unlikely" to be funded). It seems "reasonably probable" that the Final Rule threatens Plaintiffs' identified concrete and non-speculative interests. *California v. Azar*, 911 F.3d at 570.

**ii. Substantive Injury-in-Fact**

Plaintiffs have also demonstrated a substantive injury-in-fact. To estabish a substantive injury-in-fact, a plaintiff must show that they suffered "an invasion of a legally protected interest" that is "concrete and particularized" and "actual or imminent, not conjectural or hypothetical." *Spokeo*, ___ U.S. at ___, 136 S. Ct. at 1548 (quoting *Lujan*, 504 U.S. at 560). As described *supra*, Plaintiffs adequately have alleged that their member-scientists will face immediate financial expenses to conform their research agendas with the Final Rule. (Doc. 9 at 32–36; Doc. 27 at

15–17) (citing Sarnat Decl. ¶¶ 7, 9–13; J. Lewis Decl. ¶¶ 3, 21, 23, 25–26; Balmes Decl. ¶¶ 15–19). Expenses include those required to review and revise grant application materials, redesign studies, and adjust rounds of cohort recruitment to identify new study participants or provide new disclosures to existing study participants. (Doc. 9 at 32–36; Doc. 27 at 15–20) (citing Sarnat Decl. ¶¶ 7, 9–13; J. Lewis Decl. ¶¶ 3, 21, 23, 25–26; Balmes Decl. ¶¶ 15–19). Such expenses represent actual and immediate consequences for those member-scientists who are facing an impending deadline or who are actively conducting research.

**b. Causal Connection and Redressability**

To establish a causal connection, a plaintiff must establish a "more than attenuated" line of causation between the challenged action and the alleged harm. *Maya v. Centex Corp.*, 658 F.3d 1060, 1070 (9th Cir. 2011). Once a plaintiff has established a procedural injury-in-fact, it must demonstrate "only that [it has] a procedural right that, if exercised, could protect [its] concrete interests." *W. Watersheds Project*, 632 F.3d at 485. A plaintiff does not have to provide "proof that an officer would have acted differently in the 'counterfactual world' where he was properly authorized." *Collins v. Mnuchin*, 938 F.3d 553, 586 (5th Cir. 2019), *cert. granted*, ___ S. Ct. ___ (U.S. July 9, 2020) (No. 19-563).

Plaintiffs meet the requirements of causality and redressability. EPA's decision to make the Final Rule effective immediately directly is traceable to

Plaintiffs' loss of their procedural right to petition for delayed implementation under the APA. A rule that is already in effect cannot be "postponed." *Clean Air Council*, 862 F.3d at 9; *Nat. Res. Def. Council*, 894 F.3d at 113. EPA's decision to make the Final Rule effective immediately cut off Plaintiffs' procedural right under Section 705. The Final Rule's immediate effect causes immediate harm to Plaintiffs and their member-scientists who must review and revise grant application materials, redesign studies, and adjust rounds of cohort recruitment to identify new study participants or provide new disclosures to existing study participants. (Doc. 9 at 32–36; Doc. 27 at 15–20) (citing Sarnat Decl. ¶¶ 7, 9–13; J. Lewis Decl. ¶¶ 3, 21, 23, 25–26; Balmes Decl. ¶¶ 15–19).

The Court remains convinced that it can redress failure to follow proper procedure through a combination of equitable and legal remedies available to correct statutory violations. The Court can remedy the deprivation of a procedural right simply by enforcing the APA's 30-day notice requirement. There is at least "some possibility" exists that the new administration would consider Plaintiffs' petition and protect Plaintiffs' concrete interests. *See Massachusetts*, 549 U.S. at 518. It is "likely, as opposed to merely speculative" that the relief sought would resolve Plaintiffs' injury-in-fact. *Lujan* 504 U.S. at 561 (internal quotation marks omitted).

Plaintiffs have satisfied the injury-in-fact, causation, and redressability requirements of standing. *See Friends of the Earth, Inc. v. Laidlaw Envtl. Servs. (TOC), Inc.*, 528 U.S. 167, 180–81 (2000).

## II. EPA's Rulemaking

The APA generally requires a 30-day delay after publication of a final substantive rule before the rule can become effective. *See* 5 U.S.C. § 553(d). The 30-day notice requirement protects "principles of fundamental fairness which require that all affected persons be afforded a reasonable time to prepare for the effective date" of a new rule "or to take other action which the issuance may prompt." *United States v. Gavrilovic*, 551 F.2d 1099, 1104–05 (8th Cir. 1977). Congress established limited exceptions to the 30-day notice requirement. Rules of "agency organization, procedure, or practice" are explicitly exempt from the requirement. 5 U.S.C. § 553(b)(3)(A). An agency also may exempt a rule from the requirement with a show of "good cause." *Id.* § 553(d)(3).

EPA provided two justifications for its decision to make the Final Rule immediately effective on publication. EPA first asserted that the Final Rule is a procedural rule, and, therefore, stands exempt from the 30-day notice requirement. Final Rule, 86 Fed. Reg. at 472 (citing 5 U.S.C. § 553(d)(2)). EPA next found that even if the delayed-effective date requirements applied to the Final Rule, there would be "good cause" to make the Final Rule immediately effective "because

immediate implementation of the rule . . . is crucial for ensuring confidence in EPA decision-making." *Id.* (citing 5 U.S.C. § 553(d)(3)). The Court addresses each justification in turn.

**a. The Final Rule is a Substantive Rule**

"[T]he central distinction among agency regulations found in the APA is that between 'substantive rules' on the one hand and 'interpretive rules, general statements of policy, or rules of agency organization, procedure, or practice on the other.'" *Chrysler*, 441 U.S. at 301 (quoting 5 U.S.C. §§ 553(b), (d)). A substantive rule holds "binding" effect and retains the "force of law." *See id.* at 302; *see also Bullock v. Internal Revenue Serv.*, 401 F. Supp. 3d 1144, 1155–57 (D. Mont. 2019). A procedural rule governs internal agency proceedings, and "extends to 'technical regulation of the form of agency action and proceedings.'" *S. Cal. Edison Co. v. FERC*, 770 F.2d 779, 783 (9th Cir. 1985) (quoting *Pickus v. U.S. Bd of Parole*, 507 F.2d 1107, 1113 (D.C. Cir. 1974)).

A procedural rule must govern and pertain to *agency procedure*. Agency actions that go "beyond formality and substantially affect[] the rights of those over whom the agency exercises authority" are not procedural rules. *Pickus*, 507 F.2d at 1113. Past examples of procedural rules remain illustrative: an agency freeze on the processing of applications for radio broadcast stations, *see Kessler v. FCC*, 326 F.2d 673, 679-83 (D.C. Cir. 1963); an agency implementation of new processes to

accelerate applications for abandoning railroad lines, *see Commonwealth of Pennsylvania v. United States*, 361 F.Supp. 208, 220–21 (M.D. Pa. 1973), aff'd, 414 U.S. 1017 (1973); an agency process to file discrimination charges, *see Hall v. EEOC,* 456 F.Supp. 695, 702 (N.D. Cal. 1978); and an agency directive specifying that audits be performed by nonagency accountants, *see Guardian Federal Savings and Loan Ass'n v. Federal Savings and Loan Insurance Corp.*, 589 F.2d 658, 665 (D.C. Cir. 1978). These examples highlight that procedural rules provide the nuts-and-bolts procedural guidelines that allow an agency to carry out its functions. Congress exempted procedural rules from the 30-day notice requirement to "ensure that agencies retain latitude in organizing their internal operations." *Batterton v. Marshall*, 648 F.2d 694, 708 (D.C. Cir. 1980).

The Final Rule falls outside the realm of a procedural rule because it fails to provide the agency with procedural direction. It is no mere "internal house-keeping measure[]." *Batterton*, 648 F.2d at 702. The Final Rule instead makes a substantive determination of how the agency should weigh particular scientific information in future rulemakings. The Final Rule determines outcomes rather than process. The Final Rule's status becomes particularly clear when one examines what it is missing—any kind of procedure. EPA itself noted in its rulemaking that it would have to issue future guidance on how the rule operates procedurally. *See* Final Rule, 86 Fed. Reg. at 471. Such procedures include how EPA would designate key

studies as pivotal science, document the availability of dose-response data, identify conflicts with statutes, and provide a process for the EPA Administrator to consider exemptions. *See id.*

In comparison, the Final Rule easily meets the core requirements for a substantive rule. The "critical factor" a court must use to determine whether an agency has promulgated a substantive rule remains "the extent to which the challenged [rule] leaves the agency . . . free to exercise discretion to follow, or not to follow, the [rule] in an individual case." *Colwell v. Dep't of Health & Hum. Servs.*, 558 F.3d 1112, 1124 (9th Cir. 2009) (quoting *Mada–Luna v. Fitzpatrick*, 813 F.2d 1006, 1013 (9th Cir. 1987)). A rule that "merely provides *guidance* to agency officials in exercising their discretionary power while preserving their flexibility and their opportunity to make individualized determination[s]" is procedural. *Id.* But when a rule "narrowly limits administrative discretion or establishes a binding norm," it "effectively replaces agency discretion with a new binding rule of substantial law." *Id. See also CropLife Am. v. EPA*, 329 F.3d 876, 883 (D.C. Cir. 2003).

EPA's Final Rule represents a substantive rule because it narrowly limits the agency's discretion to consider certain scientific research when conducting future rulemakings. EPA bound itself absolutely when it determined that the agency "shall give greater consideration to pivotal science where the underlying dose-

response data" are "available in a manner sufficient for independent validation." Final Rule, 86 Fed. Reg. at 492. EPA further bound itself to provide "lesser consideration" to studies where the underlying dose-response data was not made publicly available—but *only* where data was not made public due to technological infeasibility or privacy. *Id.* EPA otherwise *cannot* consider studies where underlying dose-response data was not publicly available unless the EPA Administrator grants an exemption. *See id.* EPA took the additional step of limiting EPA Administrator discretion to make such decisions. The EPA Administrator only can grant exemptions on a case-by-case basis, for one of five enumerated reasons, with a written explanation on the record. *Id.* at 493. With these substantive limitations to discretion, it appears unsurprising that EPA did not consider its own rule a procedural rule when it introduced the First Proposed Rule. *See* First Proposed Rule, 83 Fed. Reg. at 18,772.

Federal Defendants argue that the Final Rule provides discretion because it "simply provides instruction to EPA employees on the relative weight it should afford certain studies in certain rulemakings." (Doc. 24 at 26). The Final Rule employs, however, clear language of requirement. The Final Rule provides that the EPA "*shall*" afford particular weight to particular scientific research. Final Rule, 86 Fed. Reg. at 492 (emphasis added). "Unlike the word 'may,' which implies discretion, the word 'shall' usually connotes a requirement." *Kingdomware Techs.,*

*Inc. v. United States*, __ U.S. __, __, 136 S. Ct. 1969, 1977 (2016). And where a rule, as here, is "couched in mandatory language, . . . a binding intent is strongly evidenced." *Gen. Elec. Co. v. EPA*, 290 F.3d 377, 383 (D.C. Cir. 2002).

Two cases provide further support that the Final Rule represents a substantive rule. In *CropLife Am. v. EPA*, the EPA issued a press release to announce that it would no longer consider third-party human studies submitted for consideration in rulemaking. *See CropLife Am. v. EPA*, 329 F.3d 876, 881 (D.C. Cir. 2003). The D.C. Circuit concluded that such an announcement restricted EPA's discretion in "clear and unequivocal language" that reflected "an obvious change in established agency practice." *Id.* at 881. The same proves true in this case. EPA sought to bind itself in future regulatory decisions through clear language published in the Federal Register. EPA signaled a shift in agency practice. The agency seeks to give less weight to studies it once considered fully.

In *Batterton v. Marshall*, the U.S. Department of Labor sought to change its methods for determining unemployment rates. *Batterton*, 648 F.2d at 706. The D.C. Circuit reasoned that the Department's rule was substantive because it "conclusively determine[d] the unemployment statistics" on which the agency could rely when it set unemployment rates. *Id.* The D.C. Circuit further elaborated that the Department's methodology left "no room for further exercise of

administrative discretion" and that it was a "critical factor in an otherwise inflexible statutory formula for allocating monies." *Id.* at 705–06.

Again, the same proves true in this case. EPA conclusively determined how it will weigh certain scientific studies based on the availability of underlying clinical data. EPA's determination provides no room for discretion, and it is a critical factor in an otherwise inflexible statutory formula for setting health-based pollutant standards in statutes like the CAA. The Final Rule presents a substantive rule because it limits agency discretion. Before the rule, EPA possessed discretion to give equal—or unequal—weight to scientific research in developing new regulations, regardless of whether a study's underlying clinical data was available. EPA now lacks that discretion.

**b. EPA Lacked "Good Cause" to Exempt the Final Rule from the 30-day Notice Requirement**

Congress provided other limited exceptions to the 30-day notice requirement, including "for good cause found and published with the rule." 5 U.S.C. § 553(d). Notice exceptions must be "narrowly construed and only reluctantly countenanced." *Alcaraz v. Block*, 746 F.2d 593, 612 (9th Cir. 1984). Courts have limited "good cause" for setting aside notice to "emergency situations," and "examine closely proffered rationales justifying the elimination of public procedures." *Am. Fed'n of Gov't Emps., AFL-CIO v. Block*, 655 F.2d 1153, 1157 n.6 (D.C. Cir. 1981); *see also E. Bay Sanctuary Covenant v. Trump*, 932 F.3d

742, 777 (9th Cir. 2018) ("Because the good cause exception is essentially an emergency procedure . . . it is narrowly construed and only reluctantly countenanced.").

"Congress intended to impose upon an administrative agency the burden of showing a public necessity for an early effective date," and an agency therefore "cannot arbitrarily find good cause." *Nw. Airlines, Inc. v. Goldschmidt*, 645 F.2d 1309, 1320 n.16 (8th Cir. 1981). Courts generally require a showing that "delay would do real harm to life, property, or public safety." *E. Bay Sanctuary Covenant*, 932 F.3d at 777. EPA asserted in the Final Rule that it found good cause to exempt the rule from the 30-day notice requirement because the rule's "goals of ensuring transparency and consistency" are "crucial for ensuring confidence in EPA decision-making." Final Rule, 86 Fed. Reg. at 472. Federal Defendants provide no argument on this justification. (Doc. 24).

EPA's limited good cause justification falls short. EPA failed to demonstrate how delayed implementation would cause real harm to life, property, or public safety. EPA failed to describe the crisis of "confidence" it sought to address. EPA failed to show a need for urgent implementation when it took more than two-and-one-half years to finalize this regulation. *See Valverde*, 628 F.3d at 1166 (holding an agency failed to show good cause when it "let seven months go by" before promulgating a rule). "Good cause cannot arise as a result of the agency's own

delay." *Nat. Res. Def. Council*, 894 F.3d at 114–15; *see also W. Oil & Gas Ass'n v. U.S. EPA*, 633 F.2d 803, 812 & n.12 (9th Cir. 1980). "[O]therwise, an agency unwilling to provide notice … could simply wait" until the last minute to "raise up the 'good cause' banner and promulgate rules without following APA procedures." *Nat. Res. Def. Council*, 894 F.3d at 114–15. EPA lacked good cause to exempt the Final Rule from the APA's 30-day notice requirement.

**c. The Court's Final Rule Analysis Raises Other Issues**

Plaintiffs make two allegations in their Complaint. Plaintiffs first allege that EPA lacked the statutory authority to adopt procedural rules under the Federal Housekeeping Statute. (Doc. 1 at 10–11). Plaintiffs further allege that the Final Rule was a substantive rule that cannot be made effective immediately on publication. *See id.* at 12–13. Plaintiffs filed a Motion for Partial Summary Judgment on the *second allegation only*. (Doc. 8). Plaintiffs seek a declaration that EPA's decision to make the rule effective immediately was unlawful and a declaration that the rule is ineffective until 30 days from the date of its publication in the Federal Register. (Doc. 9 at 43). The Court will declare as much, but such a declaration raises further legal questions beyond the scope of relief sought.

EPA asserted that it promulgated the Final Rule pursuant to its federal housekeeping authority derived from the Federal Housekeeping Statute. *See* Final Rule, 86 Fed. Reg. at 471 (citing 5 U.S.C. § 301). The Federal Housekeeping

Statute provides "a grant of authority to the agency to regulate its own affairs." *Chrysler*, 441 U.S. at 310. The statute authorizes procedural rules "as opposed to "'substantive rules.'" *Id.* at 309–10.

The Court's above determination that the Final Rule represented a substantive rule rather than procedural rule casts into significant doubt whether EPA retains any legal basis to promulgate the Final Rule. As Federal Defendants concede in their Response, "if the Court . . . concludes that the Final Rule is a substantive rule, then the rule would lack a legal basis because EPA promulgated the rule pursuant to its housekeeping authority, which only permits the promulgation of procedural rules." (Doc. 24 at 31 n.4).

Plaintiffs have not sought expedited relief on their first allegation that EPA issued unlawfully the Final Rule. Plaintiffs have limited their request for expedited relief *only* to EPA's decision to exempt the Final Rule from the APA's 30-day notice requirement. In the interest of judicial prudence, the Court will limit its Order to that issue alone.

## CONCLUSION

Summary judgment proves appropriate where the movant demonstrates that no genuine dispute exists "as to any material fact" and the movant is "entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). This case presents no material facts in dispute. Plaintiffs have met their burden and are entitled to judgment as a

matter of law based on the administrative record before the Court. The Final Rule was a substantive rule. EPA did not provide good cause to exempt the Final Rule from the APA's 30-day notice requirement. EPA's decision to make the Final Rule immediately effective on publication was "arbitrary, capricious" and "otherwise not in accordance with law." 5 U.S.C. § 706(2)(A).

**ORDER**

Accordingly, **IT IS ORDERED** that:

- Plaintiffs' Motion for Partial Summary Judgement (Doc. 8) is **GRANTED**;
- The Court declares that EPA unlawfully made the Final Rule effective immediately on publication in the Federal Register, Strengthening Transparency in Pivotal Science Underlying Significant Regulatory Actions and Influential Scientific Information, 86 Fed. Reg. 469 (Jan. 6, 2021); and
- The Court declares, therefore, that the Final Rule is ineffective until 30 days from its January 6, 2021, date of publication in the Federal Register: February 5, 2021.

Dated the 27th day of January, 2021.

Brian Morris, Chief District Judge
United States District Court

# Congress of the United States
Washington, DC 20515

January 27, 2021

The Honorable Joseph R. Biden, Jr.
President of the United States of America
1600 Pennsylvania Ave NW
Washington, DC 20500

Dear President Biden:

We appreciate your commitment to addressing the climate crisis and restoring scientific integrity across all federal agencies. Over the last four years the Trump Administration has waged an unprecedented attack on science, and we are grateful for your leadership to defend and support the scientific community. We write to express our significant concern about one particularly harmful rule finalized by the Trump Administration's Environmental Protection Agency, the "Strengthening Transparency in Pivotal Science Underlying Significant Regulatory Actions and Influential Scientific Information" rule.[1] We are grateful for your early attention to the "Censored Science" rule in your Executive Order on Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis, and we urge you to use all legal and administrative means at your disposal to rollback this harmful rule immediately.

The EPA's ability to meet its mandate to protect public health and the environment depends on science that is free from political interference, bias, or ideology, and without any conflicts of interest. We are deeply concerned that Trump's final "Censored Science" rule would severely impede the Agency's ability to protect Americans from risks to human health and the environment by limiting the scope of research that the EPA could consider in making decisions. The final rule essentially blocks access to the best available science, which could jeopardize the health and livelihood of every person in this country and disproportionately burden Black, Indigenous, and communities of color who are often still waiting for the EPA to fulfill its promise of clean air and clean water. This final rule is only the latest such attempt by regulated industry to weaken EPA's regulatory authority during Trump's Administration, and it cannot stand.

Unsurprisingly, each of the many iterations of the "Censored Science" rule has been met with significant opposition from the scientific community, many Members of Congress, and leading environmental and health organizations. The original proposed rule received nearly 600,000 public comments, most of which demonstrated the far-reaching implications and concerns that should have been but were not addressed during the rulemaking process.[2] Of note, the Presidents of the National Academies submitted public comments for the proposed rule and warned that it could "pose a threat to the credibility of regulatory science" and urged the EPA to seek

[1] 86 Fed. Reg. 469 (Jan. 6, 2021).
[2] Lisa Friedman, "EPA to Limit Science Used to Write Public Health Rules," *New York Times*, November 11, 2019, https://www.nytimes.com/2019/11/11/climate/epa-science-trump.html.

"objective, expert guidance" on the rule and offered their own assistance in reviewing it.[3] Members of Congress also called for an independent review, and yet former EPA Administrator Wheeler never followed through. Even the Agency's own Science Advisory Board expressed concerns about the rule before it was finalized.[4]

At a time when our nation is facing compounding public health and climate crises, it is deeply troubling that the rule is inconsistent with the EPA's statutory obligation to use the best available science as required in the Toxic Substances Control Act, Safe Drinking Water Act, Clean Water Act, and Clean Air Act. The rule could preclude the use of a range of scientific research that has long been used in establishing public health safeguards. The EPA rushed to finalize this significant rule in the waning weeks of the Trump Administration, violating basic provisions of the Administrative Procedure Act, which requires at least a 30-day waiting period between the finalization of a regulation in the Federal Register and the date that it takes effect.[5] We are looking forward to working with you to strengthen protections to protect our environment and public health, and rolling back this rule is an important first step.

The scientific data that would be barred from consideration under the "Censored Science" rule is vital to EPA's most critical regulations: lead in drinking water, toxic chemicals, mercury, air pollution, and many more that affect the health and well-being of our communities. The rule seeks to dismiss the value of science at the EPA; we cannot allow it to stand. To protect our nation's bedrock public health and environmental protections, we urge you to quickly make rollback of the egregious "Censored Science" rule a priority.

Thank you for consideration of our request. We stand ready to work with you and your Administration to restore scientific integrity across the federal government.

Sincerely,

Suzanne Bonamici
Member of Congress

Paul D. Tonko
Member of Congress

Donald S. Beyer Jr.
Member of Congress

Diana DeGette
Member of Congress

[3] "Academies' Presidents Comment on the EPA's Proposed Rule for Strengthening Transparency in Regulatory Science," The National Academies of Sciences, Engineering, and Medicine, July 18, 2018, https://www.nationalacademies.org/news/2018/07/academies-presidents-comment-on-the-epas-proposed-rule-for-strengthening-transparency-in-regulatory-science.

[4] Sean Reilly, Kelsey Brugger, Maxine Joselow and Ariel Wittenberg, "Advisory panel slams Trump's regulatory rollbacks," *E&E News*, January 2, 2020, https://www.sciencemag.org/news/2020/01/epa-science-advisers-slammed-agency-ignoring-science-here-what-they-said.

[5] 5 U.S.C. 553.

## ADDITIONAL SIGNATORIES

Alma S. Adams, Ph.D.
Nanette Diaz Barragán
Joyce Beatty
Earl Blumenauer
Lisa Blunt Rochester
Jamaal Bowman, Ed.D.
Brendan F. Boyle
Anthony G. Brown
Julia Brownley
Ed Case
Sean Casten
Kathy Castor
Judy Chu
Yvette D. Clarke
Steve Cohen
Gerald E. Connolly
Jim Cooper
Charlie Crist
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Anna G. Eshoo
Adriano Espaillat
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Ruben Gallego
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Chrissy Houlahan
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Betty McCollum
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James P. McGovern
Jerry McNerney
Gregory W. Meeks
Grace Meng
Gwen S. Moore
Jerrold Nadler
Grace F. Napolitano
Eleanor Holmes Norton
Jimmy Panetta
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Ed Perlmutter
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Chellie Pingree
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Mike Quigley
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Lucille Roybal-Allard
Bobby L. Rush
John P. Sarbanes
Mary Gay Scanlon
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Terri A. Sewell
Mikie Sherrill
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Abigail D. Spanberger
Haley M. Stevens
Thomas R. Suozzi
Mark Takano
Norma J. Torres
Juan Vargas
Bonnie Watson Coleman
Peter Welch
Jennifer Wexton

**Briefing: Data Transparency**
**Thursday, January 25, 2017**
**2:30 pm – Administrator's Office**

## Background

Currently, EPA is not required to use the best available science in its regulatory actions. In the past, this has led EPA to rely on science conducted by third-parties that is not publically available. In fact, in some situations, EPA does not have access to the data used to justify its own regulations. While guidance already exists to improve information quality, it has not been fully enforced. EPA should ensure that its actions are based on sound science that is transparent and can be independently verified.

## Key Examples

- **PM Epidemiology Studies:** When EPA established the 1997 NAAQS for particulate matter (PM), it relied on two studies, known as the Harvard "Six Cities" and American Cancer Society (ACS II) studies, which linked PM to certain health effects. The raw data for these studies was never made publically available. Nevertheless, EPA has continued to use the health effects from these studies as a primary source of "co-benefits" for a multitude of regulations, including other NAAQS, vehicle GHG standards, and regional haze standards. Most notably, EPA used PM health effects to derive 99% of the benefits for the MATS rule. The scientific community has identified major shortcomings in the methodologies and findings of these studies, all of which could be addressed if EPA provided the underlying data for independent review.

- **Chlorpyrifos Study:** The petition to ban chlorpyrifos relied on a study by the Columbia Center for Children's Environmental Health, which linked the pesticide to childhood developmental delays. Similar to the PM studies, the raw data for this study was never made publically available. Additionally, the EPA Scientific Advisory Panel and the USDA have criticized this study.

## Next Steps

**Deliberative Process / Ex. 5**

## Attendees

- Ryan Jackson
- Brittany Bolen
- Richard Yamada
- Clint Woods
- Erik Baptist
- Justin Schwab

The Final Strengthening Transparency in Regulatory Science (STRS) Rule
Differing Scientific Opinion
Thomas Sinks, Ph.D
Humans Subjects Research Review Official

Summary:

1. The STRS must align with EPA's Scientific Integrity Policy (SIP) because the rule instructs scientists how to select, analyze, and interpret the science underlying rulemaking.
2. The SIP supports EPA scientists providing their differing scientific opinions.
3. The [draft] final rule includes fatal flaws that will prevent the Agency from achieving its mission:
    a. The final STRS reliance on a tiered system (Secure Data Enclave) is infeasible and there is no evidence that, if established, an SDE could achieve the goal of the STRS.
    b. As a result, the weighting scheme will force EPA scientists to discount or ignore human subjects research results that include the best available science in health-based rule making.
4. EPA scientists will be unable to practice scientific integrity, our agency will develop poor health-based rules, and the public may not be protected from environmental exposures.

Findings:

***Why is the STRS subject to EPA's Scientific Integrity Policy?***

*The EPA Scientific Integrity Policy states …EPA's policymakers involve science experts on scientific issues and that the scientific information and processes relied upon in policymaking manifest scientific integrity, quality, rigor, and objectivity.*[1] EPA's Scientific Integrity Policy applies directly to the STRS because it defines how agency scientists *review data, models, and studies at the time a rule is developed or influential science is finalized.*[2]

***What qualifies me to provide a differing scientific opinion?***

The EPA Scientific Integrity Policy states …*When an Agency employee substantively engaged in the science informing an Agency policy decision disagrees with the scientific data, scientific interpretations, or scientific conclusions that will be relied upon for said Agency decision, the employee is encouraged to express that opinion, complete with rationale, preferably in writing.*

1) I have been an EPA employee since September 6, 2015 when I was hired as the Director, Office of the [EPA] Science Advisor.

2) I am the principal author of EPA's *Plan to Increase Access to Scientific Results of EPA-funded Research.*[3] In addition, I have represented EPA on the National Science and Technology Council's Open Science Workgroup and Subcommittee since 2016.

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[1] EPA Scientific Integrity Policy … https://www.epa.gov/sites/production/files/2014-02/documents/scientific_integrity_policy_2012.pdf

[2] https://www.federalregister.gov/documents/2020/03/18/2020-05012/strengthening-transparency-in-regulatory-science

[3] https://www.epa.gov/sites/production/files/2016-12/documents/epascientificresearchtransperancyplan.pdf

3) I was named by the Office of the Administrator (OA) as the Agency point-of-contact in the Notice of Proposed Rulemaking for Strengthening Transparency in Regulatory Science in the spring of 2018.

4) I participated as a member of the ORD team addressing the science issues raised in comments on the proposed rule - Strengthening Transparency in Regulatory Science.

5) In have 35 years of experience as a Federal government epidemiologist. I have conducted, analyzed, reviewed, and published human subjects research including cohort, case-control, cross-sectional, and community intervention trials. From 2005 to 2015, I was the Acting Director and the Deputy Director of both the National Center for Environmental Health at the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

6) I have served as EPA's Humans Subject Research Review Official since August 2016. I was the principal official updating EPA's revision to the Common Rule. I am the only EPA scientist that has worked to establish a tiered approach to access Confidential But Unclassified Information (CUI) using a Secure Data Enclave.

***Why is a Secure Data Enclave not a feasible mechanism for supporting the STRS?***

EPA's *Plan to Increase Access to Scientific Results of EPA-funded Research* (Plan) requires that the data underlying EPA intramural and extramural published science be made available through designated data repositories. The purpose underling the Plan is to provide researchers the opportunity to extend Federal investments in research by further analyses of the data or combining the data sets with additional data. In contrast to the STRS, the Plan is not intended to make underlying data available to external scientists to evaluate falsification or fabrication (scientific misconduct) or alternative statistical approaches to analyses.

The EPA Plan has been implemented in three phases and covers the underlying datasets of studies published after implementation. Data underling ORD intramural publications have been made available since October 2015. Data underling other intramural datasets have been made available as of October 2018. The EPA Plan does not cover datasets underlying EPA-funded publications prior to the implementation dates nor studies reviewed by EPA that were not funded by EPA (3rd party research). While every Federal Agency having a research portfolio of $100 million has published a similar plan, EPA has no agreements in place with any Federal, state, or local agency, academic institution, trade association, industry, or contract research company to host their data on EPA's data repository (Science Hub). No EPA policy order, guidelines, or regulations exist that encourage or enable EPA to collect 3rd party research data and host it in our data repository.

The EPA plan recognizes the need to promote public access while protecting CUI data. However, the plan does not establish a mechanism to promote the availability of personal identifying/health information (PII/PHI) or confidential business information (CBI). One mechanism for promoting access to CUI data is a tiered access system within a Secure Data Enclave (SDE). However, EPA has not established an SDE and lacks trained staff or funding to manage an SDE. Recognizing that the Plan implies a need to make EPA-funded CUI data available for analysis and recognizing that EPA had neither the staff expertise nor funding to create one, Greg Susanke and I established an interagency agreement

(IA) with the Data Research Center (RDC) of National Center for Health Statistics, Centers for Disease Control and Prevention. We created a pilot study using the RDC to host no more than 5 EPA intramural datasets. It took 18 months to establish the interagency agreement. At this time, one dataset underlying EPA research has been posted. We have confirmed that EPA lacks the technical expertise or training to create our own SDE. We confirmed that rigorous data management plans and data security are required. We believe the cost to use the NCHS RDC ($250K to post up to 5 sets of data for 3 years) would be prohibitive for a larger effort.

We note that our pilot was established to support the EPA Plan, not the proposed STRS rule. It seems unlikely that EPA could establish our own SDE in less than two years and without a sizable financial investment. In addition, it does not appear feasible that an EPA SDE could host datasets of 3rd party research, research published prior to 2015, or research covered by a Certificate of Confidentiality (CoC)[4]. EPA cannot mandate 3rd party research being posted on an EPA owned or shared SDE. Approval to post historic datasets must be reviewed by the original IRB which may or may not agree. In some cases, reconsent of human subjects may be required which would prevent any effort to reanalyze the published dataset. The impact of the 21st Century Cures Act may also limit the use of an SDE. Under a CoC, data sharing of PII/PHI is limited between the investigators. All NIH and CDC human subjects research conducted since the fall of 2016 when the 21st Century Cures Act was finalized is covered by a Certificate of Confidentiality. The vast majority of environmental human subjects research is conducted by agencies other than EPA.

Finally, restricting access through an SDE may fail to meet EPA's definition used in the STRS supplemental rule of public availability ... *available in a manner sufficient for independent validation*. The SDE will enable data analysis of restricted data but not access to the data. The SDE prevents disclosure of direct or indirect identifiers which an analyst may require to establish independent validation.

***Why would a weighting scheme based on underlying data unavailability result in inferior health-based rulemaking?***

Any rule or guidance that diminishes or removes high quality research from consideration in rule making results in poorly developed rules. Factors used to define high quality research are study type, design, quality control measures and how the findings fit into a weight-of-evidence supporting or refuting causation[5]. The availability of underlying data provides a platform for new research and may allow the public to verify analyses or demonstrate errors, falsification, or fabrication of the findings.
But data availability is not a measure of study quality nor is it a determinant of causation.

Human subjects research is the most predictive data for establishing the human health impact from environmental exposures. The double-blind placebo trial is considered the gold standard. Community trials also provide high quality information. Observational studies are also informative, particularly occupational cohort studies. Case-control and cross-sectional research is less informative and significant

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[4] Wolf LE, Beskow LM. New and Improved? 21st Century Cures Act Revisions to Certificates of Confidentiality. American Journal of Law and Medicine. 44(2018): 343-358

[5] Weed DL, Gorelic LS; The Practice of Causal Inference in Cancer Epidemiology. Cancer Epidemiol Biomarkers Prev 1996 Apr;5(4);303-311.

control for confounders is required. Known human carcinogens receive that classification only if high quality human health studies document an increased cancer risk.

Conclusion:

Human subjects research data are protected from unrestricted public access. The Privacy Act, Common Rule, HIPPA, and the 21st Century Cures Act all contribute to these protections. As described above, restricted access using a SDE is not a solution. A final STRS rule that diminishes or disregards highly relevant human subjects research from consideration because of underlying data availability and relies too heavily on a nonexistent SDE will result in setting aside relevant science in developmental phases of rulemaking. This will compromise the scientific integrity of our scientists, the validity of our rulemaking, and possibly the health of the American People.

**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF MONTANA**
**GREAT FALLS DIVISION**

| | |
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| ENVIRONMENTAL DEFENSE FUND; MONTANA ENVIRONMENTAL INFORMATION CENTER; and CITIZENS FOR CLEAN ENERGY,<br><br>*Plaintiffs*,<br><br>v.<br><br>U.S. ENVIRONMENTAL PROTECTION AGENCY; and ANDREW R. WHEELER, in his official capacity as Administrator of the U.S. Environmental Protection Agency,<br><br>*Defendants*. | Case No.: 4:21-cv-00003-BMM-JTJ<br><br>The Honorable Brian Morris, Chief Judge |

**DECLARATION OF LINDA S. BIRNBAUM, PHD**

I, Linda Birnbaum, declare as follows:

1. My name is Linda Birnbaum. I am a microbiologist and toxicologist by training. Between 1972 and 1989, I held several academic research posts, including positions at the National Toxicology Program (NTP) at the National Institute of Environmental Health Science (NIEHS). From 1989 to 2009, I held several positions with the Environmental Protection Agency (EPA) including Director, Experimental Toxicology Division, National Health and Environmental Effects Research Library. From 2009 to 2019, I served as the Director of the NIEHS, which is part of the

National Institutes of Health (NIH), and as Director of the NTP. Since 2020, I have been a Scholar in Residence at Duke University's Nicholas School of the Environment.

2. I am a graduate of the University of Rochester and received my MS and PhD in Microbiology from the University of Illinois. I was elected to the National Academy of Sciences' Institute of Medicine in 2010.

3. My professional career has focused on environmental contaminants and their health impacts, including research on endocrine disruptors such as dioxins, polychlorinated biphenyls (PCBs), and polybrominated diphenyl ethers (PBDEs). I have authored more than 800 peer-reviewed papers, reports, book chapters, and abstracts.

4. I am a member of Environmental Defense Fund because I believe in its mission to advocate for science-informed policy and decisionmaking.

5. I understand that EPA Administrator Wheeler signed a rule on December 30, 2020, regarding how EPA may use studies examining "the quantitative relationship between the amount of dose or exposure to a pollutant, contaminant, or substance and an effect" on human health. *See* 86 Fed. Reg. 469, 470, 492 (Jan. 6, 2021) (codified at 40 C.F.R. § 30.2) ("Rule"). This Rule imposes new restrictions on the ability of EPA to consider such dose-response data for which underlying data cannot

be made "publicly available in a manner sufficient for independent validation." *Id.* at 492 (codified at 40 C.F.R. § 30.5(c)).

6. Based on my experience as NIEHS Director I am familiar with the process NIEHS and other institutes and centers of the NIH use to evaluate and award grants. I am also familiar with the measures that scientists, universities, grant-giving organizations, and others take to protect, and keep confidential, personal information about human participants in studies.

7. Protecting the confidentiality of both the identity of, and information about, people participating in studies regarding the health effects of pollution and chemicals is a critical and integral part of any study involving human subjects. Such protections are required by laws such as HIPAA, by agreements with the participants, and by conditions placed by universities, grant-giving entities, and other responsible entities through Institutional Review Boards. Ethical considerations, and assurances provided to study participants as an inducement to participate, also mandate that personal information be kept confidential. The grant review process includes careful review of a proposal's measures to protect confidentiality and compliance with those measures as a condition of any grant.

8. As federally funded programs, NIH and NIEHS grants serve to advance the public interest by providing scientific information that can be used to improve the lives of Americans. In the area of public health, the goal of NIH- and

NIEHS-funded research is to contribute to improving health outcomes for Americans and prevent diseases due to environmental causes. An important factor in awarding grants is whether the research can contribute to the regulatory decisionmaking of federal agencies addressing public health and environmental issues, including EPA. In fact, NIEHS has funding to specifically fund grants related to Superfund sites to inform agency decision-making in those specific areas.

9. NIH and NIEHS grants are an important source of funding for scientists studying the health effects of pollution and chemicals. Environmental epidemiology is both an expensive and intensive effort. Of its approximately $800 million budget, NIEHS spends approximately $150 million on projects involving environmental epidemiology. Other NIH institutes such as NHLBI, NICHD, NCI, and the Fogarty Center also fund environmental epidemiology studies. Researchers conducting such observational human studies often have only modest financial support from their home universities and depend on NIH and NIEHS funding to pay their salaries and to support their research centers, including the salaries of other faculty, researchers, and staff who work for them. The ability to receive and sustain NIH or NIEHS funding is critical to the continued financial viability of environmental health research centers.

10. NIH and NIEHS grants are evaluated and awarded through a multi-step process. After initial screening to assure compliance with the extensive

submission requirements, an application is assigned to a peer review panel, typically based on subject matter or the specific Institute that is issuing the grant. The review panel undertakes a careful review of each application using a standard set of scoring criteria. All NIH Institutions score applications based on 5 factors: Significance, Investigator(s), Innovation, Approach, and Environment. Each factor is scored on a scale of 1-9, with a lower score being preferable. The scores are combined to provide a percentile ranking of each application and to assess the overall impact of the proposal to exert a sustained, powerful influence on the research field(s) involved.

11. After review and scoring by the peer panel, applications are reviewed by an Advisory Council or Board for the relevant Institute or Center, which reviews the scoring and evaluates each application based how it aligns with the Institute or Center's priorities and available funding. The Advisory Council makes recommendations to the Institute or Center's director for final awards.

12. NIH and NIEH grants are highly competitive. A higher (poorer) score on any individual scoring element will likely make an application noncompetitive and highly unlikely to receive a grant. Approximately 14% of the grants submitted to NIEHS are funded.

13. An important element of the scoring of grant applications for Significance by the review panel is the impact the research will have. For studies addressing environmental and environmental health issues, the ability for EPA to use

the research to inform decisionmaking is an important consideration in assessing the Significance of an application. If research is unlikely or unable to be used to inform EPA decisionmaking, or will receive limited weight in that decisionmaking, it will receive a higher Significance score and thus be unlikely to receive funding. For example, research applications that examine the health effects of specific chemicals or pollutants that could not be used by EPA would likely be considered to have less Significance than other applications that could produce results that could support agency decision-making, thus making NIH funding unlikely.

14. In addition, some grant funds are tied to specific EPA actions. For example, NIEHS has a stream of funds for grants to address problems associated with Superfund sites. The research funded through those grants is used to help EPA make decisions regarding remediating Superfund sites. If the need to protect the confidentiality of study participants would prevent the results of that study from being used by EPA, or make EPA's use uncertain, the application would receive a high Significance score and would not receive a grant.

15. Further, science is an iterative process and successive research often relies on earlier research and data. If a researcher sought a grant that relied on earlier research but could not obtain permission to make public personal data from the earlier research, that subsequent research may not be able to support EPA decision-

making or receive due weight under the rule. Accordingly, it would receive a higher Significance score and be less likely to be funded.

16. Conversely, due to long-established legal requirements and ethical standards, proposals that do not protect the confidentiality of project participants would also score poorly on the Approach element and would not be funded for that reason. Further, those legal and ethical standards would prevent Institutional Review Boards at host universities and other reviewing institutions from approving research that did not protect the confidentiality of the study subjects.

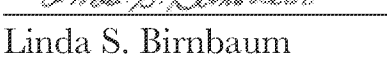
17. The consequences to researchers of not being able to obtain NIH or NIEHS grants would also be significant and in many cases immediate. Researchers would be deprived of a significant revenue stream, placing their work and the jobs of the researchers and staff they employ at risk.

18. Research itself would suffer. If researchers want to conduct research that could be considered pivotal science warranting full weight by EPA, they would be forced to request that study subjects consent to public disclosure of their personal information, including demographic, socioeconomic, and heath information. Most potential subjects would likely not consent, thus impairing the ability of researchers to conduct any research or forcing them to conduct scientifically compromised research. Alternatively, researchers will conduct research using less rigorous methodologies or focus on areas less related to public health where their research

could make a practical difference. In either case, scientific inquiry, public health, and the quality of EPA decisionmaking will be immeasurably harmed. Fundamentally, EPA would be deprived of giving full consideration to the most pertinent, sound scientific information available to make important decisions about how to address health risks posed by the environment and pollutants.

I declare under the penalty of perjury that the foregoing is true and correct to the best of my knowledge and belief.

Dated: January 7, 2021



Linda S. Birnbaum

**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF MONTANA**
**GREAT FALLS DIVISION**

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| ENVIRONMENTAL DEFENSE FUND; MONTANA ENVIRONMENTAL INFORMATION CENTER; and CITIZENS FOR CLEAN ENERGY,<br><br>*Plaintiffs*,<br><br>v.<br><br>U.S. ENVIRONMENTAL PROTECTION AGENCY; and ANDREW R. WHEELER, in his official capacity as Administrator of the U.S. Environmental Protection Agency,<br><br>*Defendants*. | Case No.: 4:21-cv-00003-BMM-JTJ<br><br>The Honorable Brian Morris, Chief Judge |

**DECLARATION OF DR. JEREMY SARNAT**

I, Dr. Jeremy Sarnat declare as follows:

1. I am an Associate Professor at the Emory University Rollins School of Public Health. My primary areas of interest are air pollution, epidemiology, and exposure assessment. My research focuses on characterizing human exposure to urban air pollution.

2. I received my Doctor of Science degree in Environmental Health and a master's degree in Public Health from Harvard University in 2001 and 1998,

respectively. I received my bachelor's degree in Anthropology from the University of Michigan in 1990.

3. I was a panelist on the Environmental Protection Agency's (EPA) Science Advisory Board for Particulate Matter, which is part of Clean Air Scientific Advisory Committee which provides independent advice to the EPA Administrator on the technical bases for EPA's National Ambient Air Quality Standards, before EPA disbanded the Science Advisory Board for Particulate Matter in 2018.

4. I am a member of Environmental Defense Fund because I believe in its mission to advocate for science-informed policy and decisionmaking.

5. My deep interest in environmental exposure science is motivated by the many epidemiologic and toxicologic findings linking air pollution to a range of adverse health endpoints. This body of research has established air pollution as a major contributor to the global burden of disease, although substantial questions remain concerning the specific pollutant sources and chemical components of the urban air mixture most responsible for the observed effects. My research focuses on these unanswered questions, investigating the factors affecting a person's exposure to urban air pollution, the impact of measurement error in air pollution exposure studies, and the associations between specific pollutant components and sources and corresponding health responses.

6. My research involves working with particularly sensitive cohorts of human subjects such as children, seniors, and individuals with cardiorespiratory disease. My studies focus on small cohorts of human subjects (one or two dozen people on a research panel). Because I work with a small number of participants, I have access to specific and reliable measures of participant exposures and associated health responses. My panel study methods have been vigorously vetted using time-tested approaches that are widely accepted in the scientific community, including peer and human subjects review and replication. Panel studies, in particular, have been shown to be important designs for addressing questions involving air pollution exposures and corresponding health response, given their use of individual-level data (*i.e.*, non-ecologic data) for both exposures and a range of clinical, sub-clinical, and molecular level biological responses. These data are often less prone to specific errors, including exposure measurement errors, that may be present in larger non-panel-based designs.

7. My study designs typically require the collection of large amounts of very sensitive, personal, and identifiable data and information about my study participants. For example, I often collect, among a suite of personal biometric data, biological information of individual metabolic profiles in plasma, breath samples, and saliva, genetic information, lung function and cardiovascular measurements, and medication usage. I also routinely collect geographic and geospatial data about

where a subject resides and their mobility patterns throughout the day; I often will utilize continuous measurement of subject location throughout a study. I also collect sensitive personal information on socioeconomic status, race, income, and diet, among other variables and information sources.

8. I conduct research in this area with the goal of ensuring that my research may be used to protect sensitive and vulnerable communities, through informing regulatory standards. My previous work has been cited and used in preparing Integrated Science Assessments, which form the scientific basis for the EPA to review its health-based ambient air quality standards, and has been used in setting the standards.

9. I am aware that the EPA Administrator has just signed a rule, effective January 6, 2021, regarding how EPA may use studies examining "the quantitative relationship between the amount of dose or exposure to a pollutant, contaminant, or substance and an effect" on human health. *See* 86 Fed. Reg. 469, 470, 492 (Jan. 6, 2021) (codified at 40 C.F.R. § 30.2) (the "Rule"). This action establishes new restrictions on the ability of EPA to consider such dose-response data for which underlying data cannot be made "publicly available in a manner sufficient for independent validation." *Id.* at 492 (codified at 40 C.F.R. § 30.5(c)). This requirement would limit EPA's ability to consider many vital public health studies, including the panel studies that I conduct, because they are based on confidential

personal information that cannot be legally or ethically disclosed—information which I would be restricted from releasing publicly by the established human subjects protections adopted by the Institutional Review Board (IRB) of my research institution, and most every other IRB with which I am familiar.

10. I would experience the effects of the Rule immediately. I am currently developing a grant application to submit to the National Institutes of Health ("NIH") for its February funding cycle for research that would involve human subjects. The application is due by February 5, 2021. The study for which I am seeking funding will use a panel study design to look at metabolic changes in asthmatics following exposure to traffic pollution. This research would seek to understand what biological mechanisms might be involved in how asthmatics respond to traffic pollution and would lead to an understanding of the susceptibility of vulnerable subpopulations to this type of exposure, as well as an understanding of what levels of exposure may be safe. I believe it would be considered "dose-response data" under the Rule. EPA currently has a network of near-road monitoring sites because the agency is concerned about health impacts from traffic pollution. My research, for which I am seeking NIH funding, would contribute to understanding safe levels of exposure to traffic pollution for particularly vulnerable groups, such as individuals with respiratory disease. In light of EPA's interest in this area, my hope and expectation

is that this work could constitute "pivotal science" that could help inform EPA's determination of appropriate health-based air quality standards.

11. The Rule will have immediate consequences for the viability of my grant application as planned. First, and most significantly, I understand that NIH considers the significance or impact research will have in making its funding decisions. If I were to keep my panel subjects' data confidential, under the Rule, my study would not be accorded its full weight as "pivotal science." That would have the potential to limit the likely impact of my research because it would be unusable or of limited use to EPA policymaking and, consequently, less likely to be funded by NIH. Addressing this problem by failing to guarantee subject confidentiality would subject my research protocol to being rejected by my (or any) IRB —and even if I could, I would incur considerable expense in ensuring that my data complied with the onerous requirements set forth in the Rule. The upshot is that the Rule puts me in an untenable position, unable to adopt an approach that would ensure grant funding of a viable panel study. If the Rule stands, I would be forced to choose between pursuing a protocol that would allow for EPA consideration and maximize the likelihood of NIH funding, but would be unlikely to obtain IRB approval—and a path of being able to get IRB approval, but making the study of limited value to EPA and unlikely to be funded by NIH.

12. Conversely, if the Rule were not in effect, I would not be faced with that dilemma. Based on previous experience with the Federal grant submission and approval process, I would expect to be more likely to receive funding and IRB approval, facilitating research to continue within my lab.

13. Failing to receive grant funding would have immediate consequences for my lab. My grant proposal will seek approximately $3-5 million in funding. This funding would likely support three to five staff and/or students and post-doctoral fellows at Emory University. If the grant were withheld because of the Rule's restrictions on EPA's consideration of the data or because a new design made the study less scientifically valuable, or if I decided I could not legally or ethically pursue the project consistent with the purpose of informing protective regulation, those jobs would be at risk.

14. Because of these concerns with the Rule, it will affect how I write the grant. To be able to expect grant funding and to ensure I could protect the jobs in my lab, I must represent that my research could be used as pivotal science, including in standard-setting processes for air pollution. But because the Rule will make that impossible with my planned panel design, I will have to substantially alter the protocol I have developed. This will take time and effort and ultimately could be fruitless. Abandoning the panel design would make my study less scientifically feasible because the analyses I propose to conduct are wholly based on

understanding individual-level exposure and response. Moreover, it is far from clear that even that redesigned study could be approved given the limited time I have available in which to rework my research approach.

15. More broadly, the Rule would not just affect my work on this study. I would have to consider shifting away from designing panel-based studies in the future, substantially changing the approach for which I conduct research and upon which I have built my career as an environmental health scientist. Because I want my research to continue to inform standard setting and policy (as it has previously), and because recruiting human subjects and receiving IRB approval for a study which would require release of sensitive biological information would be extremely difficult, I would dramatically rethink the type of designs that I use and the papers I write and pursue. Indeed, the irreconcilable choice the Rule would create—between having my research be able to inform EPA standard-setting and performing a study that could meet ethical and IRB requirements by keeping personal information confidential—would change the type of research I conduct and mean that there was certain research that I would decide not to do. As a consequence, the Rule would fundamentally undermine my ability to conduct research to contribute to setting health-protective air pollution standards.

16. On a personal and professional level, I have reached a stage in my career where I will soon be assessed for promotion to the rank of Full Professor.

Promotion will be based, in no small part, on my continuing and future ability to design and conduct relevant environmental health research, write and obtain federal funding from agencies such as NIH and EPA, and share the findings of this work with a diverse range of stakeholders, including, importantly, those in this country involved in developing policy and setting the standards related to the pollutant exposures I study, including in particular EPA.

I declare under the penalty of perjury that the foregoing is true and correct to the best of my knowledge and belief.

Dated: January 7, 2021

Jeremy Sarnat

**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF MONTANA**
**GREAT FALLS DIVISION**

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| ENVIRONMENTAL DEFENSE FUND; MONTANA ENVIRONMENTAL INFORMATION CENTER; and CITIZENS FOR CLEAN ENERGY,<br><br>*Plaintiffs*,<br><br>v.<br><br>U.S. ENVIRONMENTAL PROTECTION AGENCY; and ANDREW R. WHEELER, in his official capacity as Administrator of the U.S. Environmental Protection Agency,<br><br>*Defendants*. | Case No.: 4:21-cv-00003-BMM-JTJ<br><br>The Honorable Brian Morris, Chief Judge |

**DECLARATION OF JOHNNYE LEWIS, PH.D.**

I, Johnnye Lewis, declare as follows:

1. My name is Johnnye Lewis. I am a Research Professor at the University of New Mexico in the College of Pharmacy, Department of Pharmaceutical Sciences. I am the Director and Founder of the Community Environmental Health Program (CEHP) in the College of Pharmacy. I am also a Director of the Center for Indigenous American Environmental Health Equity Research (Indigenous EH Equity), a partnership including Crow, Sioux, and Navajo communities and agencies; and of the Navajo Birth Cohort Study/Environmental influences on Child

Health Outcomes (NBCS/ECHO), a community-driven study begun to examine how environmental exposures affect birth outcomes and child development on the Navajo Nation, and now also part of the national NIH ECHO multisite initiative; and Director of the UNM METALS Superfund Center—the first Superfund Research Center focused entirely on Indigenous communities.

2. The focus of my research over my more than 30 years as a toxicologist has been on understanding the environmental causes of chronic disease in communities, and to partner with communities, governments, and clinical care providers to develop evidence-based strategies and take actions to mitigate exposures and lower the prevalence of related disease. I have focused in particular on environmental exposures in Indigenous communities. More than 100 peer-reviewed papers on these issues have resulted from these community-partnered initiatives over the course of my career.

3. For more than 30 years, I have worked on Navajo uranium exposure and health issues, initially as a consultant to the U.S. Department of Energy developing Indigenous American risk scenarios and baseline risk assessments for Uranium Mill Tailings Remedial Action sites on tribal lands; then, through one of the first NIEHS Environmental Justice grants, collaboratively developing the Diné College Uranium Education Center; and, more recently, as Principal Investigator for the community-based DiNEH Project examining, for the first time, community

uranium exposures and health outcomes in older generations with chronic exposures. I have facilitated and developed tribal risk assessment scenarios in USEPA Regions 6, 8, and 9 working with state, tribal, and federal agencies, as well as communities.

4. The research centers that I currently direct—Indigenous EH Equity, NBCS/ECHO, and UNM METALS—all have a specific emphasis on uranium- and mine-waste exposures on tribal lands. I have led a cooperative team that includes health scientists, toxicologists, geochemists, geographers, engineers, statisticians, NGOs, community researchers, Navajo Area IHS, and Navajo Division of Health to design and obtain approval for research protocols, and implement and analyze results from three generations of Indigenous cohorts. Through my decades of work with tribal populations, I have come to have an understanding of the complexity of cultural and environmental contributors to health in tribal populations; an appreciation of jurisdictional complexities; and an ability to facilitate working relationships respectful of those boundaries which rely heavily on establishing mutual trust relationships.

5. My work conducting public-health-focused toxicology research in partnership with communities has been recognized locally and nationally by environmental and public health agencies, including appointment to the regional Air Quality Control Board; co-leadership of a Kellogg Foundation-funded

Environmental Health Task Force reporting to the New Mexico Secretaries of Health and Environment; and invited testimony to Tribal Councils, state legislative committees, and Congressional committees. I have held an elected office in the Society of Toxicology, and served on a Blue-Ribbon Panel to the NIH director and on the team selected to review and make future programmatic recommendations on the NIEHS Superfund Basic Science Research and Training Program. I was awarded the Griff Salisbury Award by NM Environmental Law Center for developing and defending a community-based recommendation reducing the uranium groundwater standard by orders of magnitude, and have just been awarded the 2021 Public Communication Award by the national professional association for toxicologists, the Society of Toxicology.

6. My spouse and I are members of the Environmental Defense Fund and have long supported its mission through donations and otherwise. As a scientist, and a toxicologist in particular, I share EDF's mission of using science to inform action to address environmental issues and to protect the health of affected populations. An important aspect of my work is collecting scientifically sound data and translating results effectively to government agencies, including the EPA, to inform evidence-based environmental and public health decisions. I make this Declaration as an EDF member and in my individual capacity and do not intend to represent the views of my funders, employers, or others.

7. I am familiar with the new EPA rule "Strengthening Transparency in Pivotal Science Underlying Significant Regulatory Actions and Influential Scientific Information" published in the Federal Register on January 6, 2021, which addresses how EPA may consider or rely upon studies which assess "the quantitative relationship between the amount of dose or exposure to a pollutant, contaminant, or substance and an effect" on human health in setting standards or developing "influential scientific information." *See* 86 Fed. Reg. 469, 470, 492 (Jan. 6, 2021) (codified at 40 C.F.R. § 30.2) (the "Rule").

8. I am deeply concerned that the Rule misrepresents the concept of transparency in science. Transparency in reference to science does not rely on access to individual pieces of data, many of which are protected by a body of laws that has developed to ensure populations that their privacy will be protected if they participate in research. Instead, the validity and transparency of science relies on the transparency of methods, compliance with federal laws on conducting research in human populations, and the transparency of analytical methods used. That occurs through review by other scientists (peer-review), review by Institutional Review Boards (IRBs) charged with protecting individual rights to privacy, and the clear description of the data used in the analyses so other investigators can replicate the work. Replication is done through evaluation of appropriateness of the methodology, not simply taking the raw data and showing it can be run through the same code to

get the same results. The Rule's misguided understanding of transparency will have real adverse consequences, impairing our recruitment of research subjects and communities and reducing the representation of Indigenous and other marginalized communities in research.

9. To begin with, ensuring confidentiality—and trust that researchers will respect it—is key to obtaining community and participant consent for involvement in population research. In my experience, study participants—particularly members of historically oppressed or disenfranchised communities, such as Indigenous communities—have learned to become wary about how information about them is used, particularly by government agencies who have not always acted in their best interests. In the cases of Indigenous sovereign nations, protections on how information on tribal members is gathered and used have been codified into policies and laws to protect individual and tribal rights.

10. In some communities this is based on fear of individual abuse, such as the cases that led to federal research policies requiring training on human research ethics for all investigators supported by federal funding. A key example is the Tuskegee Syphilis Study which hid the fact that Black participants were studied for the "natural course of syphilis," and denied treatment they were led to believe they were receiving. In other communities, distrust of research stems from violation of the scope of specific research consents. For instance, in one case, study participants who

were members of the Havasupai Tribe consented for researchers from Arizona State University to use their biological samples to study diabetes—but the researchers ultimately conducted secondary genetic analyses of those samples, and used those analyses to publish on tribal migration, inbreeding, and schizophrenia without permission from the tribe or individual participants. Although the tribe won the resulting court settlement, damage to its members' privacy rights couldn't be undone—and continuing concerns among Indigenous populations about the use of data beyond their consent have made it more difficult to recruit Indigenous people in future research, leading to bias on the applicability of research-based decisions to Indigenous or other vulnerable populations.

11. As I have discovered over decades of research, because of these concerns, members of Indigenous communities are often very reluctant to participate in any study or provide any information about themselves out of fear of how that information may be used, or misused, against them. It is critical, especially when working with these communities, that population researchers be able to assure study participants that their participation and associated data will remain confidential to be able to conduct the scientific work often necessary to help solve the very problems that contribute to disparities in health.

12. But over time, we have come up with an approach to navigate these challenges. Population studies are always designed and carried out to prevent the

disclosure of confidential and personal information about individual study participants. The specific measures to protect the privacy of study participants in population health studies are reviewed, modified, and approved by review boards generally called Institutional Review Boards, or IRBs. These boards are certified federally, and increasingly Indigenous nations have established their own federally recognized review boards, or other processes to ensure tribal privacy laws are respected by proposed research. A given study, therefore, may be subject to more than one IRB. For example, a researcher may need IRB approval from her own university, from an additional IRB providing review for large multi-institutional studies, as well as from a tribal IRB (or tribal equivalent) to assure compliance with tribal laws to protect both the privacy of tribal members and the treaty rights granted by the US government to these sovereign nations. In these cases, the sovereignty of the tribal nation also mandates that the data remain the property of the tribe, and that all data are used by the researcher under the strict protocol approved, and returned to the tribe once the study is complete, with tribal review before final publication in peer-reviewed scientific journals as well.

13. The measures tribes implement (whether through IRBs or otherwise) to protect against the misuse and disclosure of confidential information about the tribe and its members are often referred to as "data sovereignty." These measures are notably strict. By way of illustration, in a recent study involving the Navajo Nation,

nearly 2.5 years of negotiation were required to establish adequate data protection by the joint data analysis center for a multisite federal study to ensure the terms of the tribal research policy, the privacy of tribal members, and the other terms of approval of the research would be protected while allowing for data to be compared in analyses to other sites in the study to better inform the understanding of needs in the population.

14. In addition to IRB conditions, the need to protect research participants' privacy has been recognized and supported by state and federal laws, such as HIPAA, as well as by agreements with study participants acknowledged in the study consent forms approved by federally certified IRBs.

15. Trust is a key factor in all of this; we cannot do our work without it. It is essential to obtaining approval from tribal IRBs, obtaining agreements with tribes to perform research studies, and obtaining consent from individuals to participate in studies. Building that trust takes years of work and a proven history of honesty and meeting commitments. I have worked with the Navajo Nation and several other Indigenous communities for over 25 years on health-related issues and have built their trust that I will keep their personal information confidential and honor the letter and the spirit of the agreements we enter into. Without that trust, I would not be able to obtain the approvals necessary to collect and use the data. And even with that

trust, obtaining approvals requires thoughtful design of protocols, is sensitive, and takes time and care.

16. Over the past 20+ years, the scientific research community has developed a substantial awareness of these trust issues. As environmental justice has developed as an area of interest for research and as Indigenous nations have established the need for tribal consultation by federal agencies for decisions impacting their health and culture, both peer reviewers of grants and decision-makers in funding agencies have an expectation that proposals will demonstrate the investigative team's ability to conduct the research—and especially the team's sensitivity to community trust. Proposals require letters of support for the relevance of the research to the community and a plan to ensure the privacy and protection of culturally sensitive information while conducting valid scientific protocols. In my experience, none of this would be possible without a community's underlying trust that I can and will protect the confidentiality of the data I collect. Nor would I be able to get the support and consent of the tribes or individuals to participate in the study or collect the data without these guarantees.

17. But while the hard-won trust of tribal communities must be built up over decades, it can be easily lost in a moment. If I can no longer demonstrate that individual-level data will not be disclosed or will not be provided to EPA or other entities, I and my teams will lose the mutual trust we have developed with community

partners, and lose the willingness of both the tribal government and the individual community members themselves to participate in research. By its nature, trust once lost can be virtually impossible to regain.

18. But this is precisely the problem the EPA's Rule introduces. Indigenous communities participate in research because they want results to inform policies that protect their health and environment. But if according the results full weight in decisions also requires loss of privacy and confidentiality protection, or loss of ownership of data, that loss of sovereign protection will jeopardize participation.

19. And the Rule, and the loss of trust it occasions, will have even more far-reaching consequences. There is currently a strong need to achieve greater diversity in research populations to better expand the generalizability of the toxicologic research that informs our understanding of risk across populations. But losing the trust of these communities will make it very difficult to plug this gap, discouraging communities—including those targeted by active programs currently in development—from working with researchers to meet this need. And the problem is likely to persist. If trust between researchers and communities is damaged, these relationships are not quickly rebuilt, and we are likely to continue facing difficulties ensuring that research in under-studied communities goes forward. Accordingly, by reducing the willingness of vulnerable populations to participate in scientific research and blocking opportunities to understand unique responses to toxicants within these

populations, the Rule will impair our ability to develop evidence-based policies protective of these and other vulnerable populations. As a result, the research used to inform decisions will continue to fail to include the full range of populations and communities affected by those decisions. Exclusion of specific sectors of the population from the general body of science informing decisions and policy produces a strong chance of bias in the data and resulting policy, and a high risk of policies that fail to protect specific populations with unique practices or sensitivities that would produce alternate results if included.

20. These problems will immediately affect my own work. Our research centers employ approximately one hundred people, many of them members of Indigenous communities. The funding used to employ these people comes primarily from grants from several institutes at the National Institutes of Health, with a significant portion of funding tied to our UNM METALS Center.

21. Currently, UNM METALS is working with communities on Laguna Pueblo near the abandoned Jackpile uranium mine on the Superfund National Priorities list, as well as several communities on Navajo Nation where abandoned uranium mine waste from more than 520 mines active during the Cold War is being addressed under CERCLA emergency response authority through the USEPA Five (and now Ten) Year Plans to Address Uranium Contamination on the Navajo Nation. By understanding the detailed environmental conditions at these sites, as

well as the relationships between exposures and health effects, the METALS research is focused on developing novel remediation approaches and clinical interventions that reduce toxicity, provide cost-effective and sustainable solutions for remediation, and improve health. An initial clinical trial to reverse DNA damage has already begun. UNM METALS's work is being funded in part by a multi-year grant from the National Institute of Environmental Health Sciences. My team and I are preparing a proposal to continue that funding, which provides significant support for the UNM METALS team, for submission in February 2021 as part of a call for proposals that occurs every two years. As many as 40 research teams working on questions affecting Superfund sites and vulnerable exposed populations across the country are expected to respond.

22. In UNM METALS's research, individual-level data are collected while monitoring health and exposures in communities. Analyses to develop conclusions require large numbers of individuals in the population for validity of the science. Studies reporting only "case studies," or work based on a single individual, would not be considered representative of the population and sufficient to inform decisions. For the peer review conducted for publication in scientific journals, the summary-level analyses that form the basis for our understanding of the relationships between exposures to contaminants and toxicity need to be representative of the affected populations. That peer review and determination of validity will be based on the

details of the methods used to collect the data and the analyses performed. Considerations include study details like how participants in the study were identified, whether as a whole they represent the population or are biased in some way, whether they understood the research that was being conducted, and whether valid methods were used to analyze the data. To pass muster, the data need to include a range of ages, men and women, rich and poor, and the racial and ethnic make-up of those who will be influenced by the results to be generalizable to that population. By contrast, the data related to a given individual in that group will not be the basis for drawing any valid conclusions.

23. Much information that is collected in clinical trials, or from medical record review, is clearly very personal and sensitive. In my experience, that is the kind of personal information that Indigenous, and most other, communities and individuals view as particularly private and sensitive and that Indigenous communities by right of sovereignty protect through IRB conditions and other agreements. If we cannot commit to keep the underlying data confidential, the tribes are not likely to continue to provide access to the data and their members will be unlikely to consent to participate, placing the entire study, and grant, in jeopardy, and also resulting in tribal-specific data being unavailable to inform decisions on tribal land. It is unlikely that we could obtain IRB or tribal approval to disclose that confidential data to EPA. Conversely, however, it we cannot explain that EPA will

be able to place due weight on the results of the study to inform its policy and decision-making, it is unlikely that my team's proposal will meet the expectations of the funding agency, or the partnering tribes and communities. These competing demands—between the confidentiality necessary to perform the work and the disclosure that would be necessary for results to be used to inform EPA decisions, and therefore to receive funding for the work—are untenable.

24. Proposals for large centers such as UNM METALS that are meant to address complex issues through multidisciplinary team science require many months of preparation. The work proposed is developed in consultation with the communities and tribes involved to identify gaps in knowledge, requires access agreements and support from the tribes and communities, and requires integration across 9 individual projects that learn from each other and ultimately develop perspectives not possible within individual research projects.

25. Currently, UNM METALS is preparing a proposal seeking a >$10 million 5-year grant to the National Institute of Environmental Health Sciences in response to their CERCLA mandate to develop science that informs USEPA's CERCLA responses. That proposal is due on February 15, 2021, and the components are in close-to-final draft form and out for review by external advisors to inform final edits. Budgets for research components and subawards to collaborating institutions and NGOs are being finalized. The proposal is dependent on continued access to

data and participation from the Navajo Nation and Laguna Pueblo. But because of the Rule, it will now be much more difficult to obtain that access. I now must explain to the tribes and their members that I would be required to provide underlying individual data from the research studies to EPA in order for the data to receive full weight in EPA decision-making. And not only are they unlikely to consent to that arrangement, but posing the choice risks destroying the trust I have built up over many years and thereby losing the trust of the tribe and individuals permanently. All this—plus the EPA Rule's sudden effectiveness— means we face the immediate challenge of scrambling to figure out how to rebuild the study (well over 1000 pp) to somehow be able to answer the questions on toxicity resulting from exposures while accommodating both EPA requirements and tribal concerns. This will take enormous time and effort. And it is extremely unlikely that such changes could be made in time to meet the February 15 deadline, jeopardizing the funding of the more than 65 people funded by this center alone, and the expectation of partner communities to improve the understanding of these situations and possible options to reduce hazards and improve health.

26. If UNM METALS were to lose the existing NIEHS grant, or not obtain the additional grant, UNM METALS would face an immediate financial crisis and be forced to lay off much, if not all, of its work force.

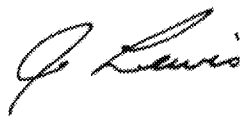
27. And science itself will suffer. If these tribal-specific and site-specific data are NOT included in decisions, the decisions will not be based on the best and most relevant data to protect the populations.

28. This goes beyond just my work and the specific grants discussed above. Once tribes and other communities learn that researchers in general cannot promise to both keep the individual data confidential and still provide actionable data to EPA, researchers lose not only their funding and the opportunity to apply their research expertise to help solve these complex problems, but also lose the trust they have built up over the years and access to those communities and individuals needed for science to be truly representative of the populations affected by research results—a goal we must achieve to ensure the validity of research and the ability to generalize results to specific populations. Further, researchers will face additional challenges gaining the trust of new communities to conduct new research if protection of individual and tribal privacy policies cannot be guaranteed. In either case, without the ability to protect confidential data, population researchers will not be able to perform the kind of work necessary to document the health impacts of pollution and inform decisions by EPA to address those critical environmental health issues and protect the health of communities.

29. The Rule also jeopardizes my ability carry out the work that is so important to me personally and professionally. In my decades of working with

communities and with agencies involved in decision-making that affects environmental quality and population health, I have learned how important it is to maintain communication and partnership with all parties involved to ensure that communication is effective. In doing these large multi-disciplinary, multicultural projects, one role I have always played is to bridge disciplines and cultures, keep people at the table and discussing concerns, translating to make sure that intentions are accurately heard by audiences, and that effective communication continues across involved parties. The situations I work in are often emotionally charged, and frustrations resulting from decades of inaction on one side, and constraints on what is possible to accomplish on another, further increase tensions. As someone who has had a very diverse history in working with diverse communities, academic research, and regulatory agencies, and tried hard to build strong and trusted partnerships, it is important to me to be able to continue the work we have started to contribute to resolving these complex situations. My professional career, and a large part of my personal life, have been committed to these goals, and I feel very responsible for those who work as part of my research teams, and to those in communities who have trusted our ability to find answers to these challenging questions. Losing that base that has taken decades to build would create enormous personal and professional loss.

I declare under the penalty of perjury that the foregoing is true and correct to the best of my knowledge and belief.



Dated: January 8, 2021

Johnnye Lewis

**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF MONTANA**
**GREAT FALLS DIVISION**

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|---|---|
| ENVIRONMENTAL DEFENSE FUND; MONTANA ENVIRONMENTAL INFORMATION CENTER; and CITIZENS FOR CLEAN ENERGY,<br><br>*Plaintiffs*,<br><br>v.<br><br>U.S. ENVIRONMENTAL PROTECTION AGENCY; and ANDREW R. WHEELER, in his official capacity as Administrator of the U.S. Environmental Protection Agency,<br><br>*Defendants*. | Case No.: 4:21-cv-00003-BMM-JTJ<br><br>The Honorable Brian Morris, Chief Judge |

**DECLARATION OF DR. JOHN R. BALMES**

I, John R. Balmes, M.D., do declare and state as follows:

1. I am a Professor of Medicine at the University of California, San Francisco (UCSF), where I have been on the faculty since 1986; and since 2002, also a Professor of Environmental Health Sciences at the School of Public Health of the University of California, Berkeley (UC Berkeley). I am an Attending Physician in Pulmonary and Critical Care Medicine and in Occupational and Environmental Medicine at the Zuckerberg San Francisco General Hospital. I received my M.D.

from Mount Sinai School of Medicine. A copy of my National Institutes of Health biographical sketch is appended to and included as part of this declaration.

2. For over 40 years I have been studying the effects of exposure to various occupational and environmental agents on respiratory, cardiovascular, and metabolic health. My current primary areas of research interest are occupational and environmental respiratory disease, the effects of exposures to various air pollutants on respiratory and cardiovascular health, exposure-response relationships, and air pollution contributions to the metabolic syndrome. Of specific interest, I am one of the multiple principal investigators of a Children's Environmental Health Center grant through the National Institute of Environmental Health Sciences (NIEHS)/Environmental Protection Agency (EPA) to study the adverse effects of air pollution on children living in Fresno, in the San Joaquin Valley. Among the peer-reviewed studies published from that effort, is John R. Balmes, *et al.*, *Polycyclic aromatic hydrocarbon exposure and wheeze in a cohort of children with asthma in Fresno, CA*, 22 J. Expo Sci. & Environ. Epidemiol. 386 (July 2012). I am currently the contact principal investigator of an NIEHS R24 Environmental Epidemiology Cohort Maintenance grant to update and continue following the Fresno cohorts.

3. In addition to my medical professional work, I also serve as the Director of the Northern California Center for Occupational and Environmental Health. I serve on the Editorial Board and as Associate Editor of the *American Journal of*

*Respiratory and Critical Care Medicine*. I am affiliated with several professional organizations, among them the American Thoracic Society (ATS), of which I have been an active member since 1980, participating on a number of committees, including four years of service on the ATS Board of Directors. This past year, I received the ATS Distinguished Achievement Award.

4. I am the Physician Member of the California Air Resources Board. I also actively advise other governmental agencies at the local, state, and national levels regarding air pollution health effects, climate change health effects, and occupational health. That work is important to me personally, and it is also important to me that my research is useful in public policy decision-making, as it has been on multiple occasions. For example, some of my research was relied on in setting the National Ambient Air Quality Standards for Ozone, in 2015. *See* 80 Fed. Reg. 65,292, 65,449 (Oct. 26, 2015).

5. I was a member of the EPA Clean Air Scientific Advisory Committee Particulate Matter Review Panel that was formed in 2015 to augment the expertise of the Clean Air Scientific Advisory Committee and support its 2015-2020 review of the National Ambient Air Quality Standards for particulate matter. While our Panel was dismissed by press release in October 2018, right before the draft science assessment for the most recent review of the particulate matter standards was released by the Agency, I and the other members of the Panel formed the

nongovernmental Independent Particulate Matter Review Panel, and continued as citizen volunteers, to review the science and provide advice in the record for the EPA Administrator.

6. I am currently, and for many years have been, a member of the Environmental Defense Fund as I strongly believe and support its mission to advocate for science-informed policy and decision-making. I provide this declaration in support of efforts by the Environmental Defense Fund to halt U.S. EPA's attempt to limit the science the Agency can rely on in making decisions concerning the public health effects of pollution exposures.

7. Physicians and scientists undertake environmental epidemiology studies of the kind I lead and collaborate on by systematically following, over time, groups of people (cohorts) with similar characteristics and/or exposures to environmental pollution. Using data from a cohort, scientists can investigate not only the original research question, but also new research questions. Creating and maintaining a research cohort, and obtaining approval for it and for the work to be done with it, is a significant investment of intellectual capital, time, and commitment for members of the research community. At the most fundamental level, creating a human health study cohort requires the identification of persons willing to participate in our research, and securing their agreement to offer their personal health and other information to us.

8. For any study using data from a cohort, I and my colleagues on a study must obtain Institutional Review Board (IRB) approvals from our institutions prior to embarking on the study. The IRBs at both UCSF and UC Berkeley have very strict rules regarding confidentiality of research data collected through human health studies, especially for any personally identifiable information. Considerable investigator and staff effort is required to develop the confidentiality component of a study protocol that meets IRB approval. Any data sharing outside of the study investigative team must also involve IRB approval and data sharing outside of the institution requires a formal agreement. When such an agreement is signed, it almost always excludes personally identifiable information. Considerable investigator and staff effort is required to develop and manage a data sharing agreement.

9. The nature of my own public health research therefore requires that I collect sensitive personal information from study participants, and enter into contractual agreements with them (or in the case of children, with their parents/families), guaranteeing its confidentiality. The specific kinds of information I collect from members of a study cohort can include very sensitive, personal, and identifiable data and information, such as biological information about individuals, including blood, urine, saliva, hair and nail samples; lung function measurements; height and weight; and other biometrics. I also collect geographic and geospatial data about where participants live, including their exact residential addresses and

where they go; I often have almost continuous measurement of their locations throughout a study. And I collect sensitive personal information such as socioeconomic status, race, and income. For example, in the Fresno children's health study I reference above, and another of my current study cohorts as well, the majority of the participants are Latinx, and in some cases are undocumented residents. Their undocumented status is an important characteristic for the study (for example, one of my study research questions involves the relationship between psychosocial stress of undocumented status and adverse outcomes from air pollution exposures). While study participants typically agree that the results of the study can be made public, including information in the aggregate, I agree with them that I will not disclose any information that could lead to them being personally identified as part of the study cohort.

10. Given the sensitive nature of this information, in my experience, it is unlikely that individuals would agree to participate in a study in which I could not guarantee this degree of confidentiality. The ability to maintain the confidentiality of participants' information is therefore necessary to securing their participation in the study. Being able to provide that assurance is also important to me because the institutions I am affiliated with, the University of California at San Francisco and the University of California at Berkeley, require complete confidentiality as a condition of their IRB approval of my research work, as noted above.

11. Because some of my current work involves health effects in children living in a particular environment, I also must continually recruit study participants as the members of the cohort "drop out" over time. To do this, I work with the children and their families to establish their trust and to enter agreements to ensure the confidentiality of their data.

12. One important reason cohort members want to participate in the work we do, and agree to share their personal health and other information with us, is that they hope to have a positive impact and help make change—to be a part of work that can improve the environmental conditions where they live and work. And that is also why I do the research I do—it is in part for use by the government, at all levels, in setting air quality and other environmental standards, to improve the lives of all of us.

13. I am aware that the EPA proposed in 2018, and again in 2020, a rule that was announced by the EPA Administrator on January 5, 2021, and which states that the EPA cannot give full (or "great") consideration to dose-response studies, which it defines to include the kinds of human cohort-based public health studies of pollutant exposure I do, to support important public policies and significant regulatory actions unless the public at large has access to the cohort data and models underlying the study. *See* 86 Fed. Reg. 469, 470, 492 (Jan. 6, 2021). The EPA also suggests that a restricted form of access to the data and models—to allow others who

are not involved in the initial creation of the study to exactly reanalyze the same data—may be sufficient to allow the EPA to continue using peer-reviewed published dose-response research results. Furthermore, I understand that EPA has declared the Rule to be effective immediately on publication in the Federal Register, which I understand occurred on January 6, 2021.

14. In effect, this Rule severely restricts EPA from considering many vital public health studies that are based on confidential personal information that cannot be legally or ethically disclosed, including the work I am currently doing. Unless I disclose the data and information, EPA may not afford my work full weight in informing its policy choices or regulations.

15. Both I and my work are immediately harmed by the Rule. I am right now in the process of actively recruiting additional cohort members for the recently funded additional work on our Fresno study discussed above. It is important to me—and to many of my study participants—that my work be able to serve as pivotal science and receive the highest possible weight at all levels of EPA decision-making. In order to ensure this remains possible given the new requirements in the Rule, I will immediately need to inform potential study members and their families either that the research results will receive reduced weight and be less likely to impact EPA decision-making that could improve conditions for them, or that if it is to receive full weight, I cannot guarantee that their personal information will remain confidential.

As discussed below, either course will mean that it will be difficult for me to recruit enough participants for my study and will have to expend significantly more resources attempting to do so.

16. For one thing, it will not be an option to de-identify the data on which my study is based. While there are in theory methods to "de-identify" data, as EPA says in the Rule could be done to allow access to the public to reproduce my study results, because of the geographic focus of my work, and the characteristics of the cohort members, it actually will be almost impossible to maintain their confidentiality even under the protocols the Rule assumes can be used. In fact, this is a problem for most such environmental health research. Several peer-reviewed studies have shown that, particularly for the kinds of cohort data I work with—specifically, data containing specific geographic identifiers—data can be traced back to a particular individual, even where data are released under so-called "restricted access in a manner sufficient for independent validation" as referred to by the Rule. Sweeney, *et al.*, have published such work, for example. L. Sweeney, et al., *Re-identifcation Risks in HIPAA Safe Harbor Data: A Study of Data from One Environmental Health Study*, Tech. Sci., August 28, 2017, *available at* http://techscience.org/a/2017082801. In this era of "big data," it is too easy for large institutions such as the government to cross-reference data from multiple sources to make the connections necessary to associate the results of my studies with the individual participants. Once data are

made public, even in this form, they cannot be recalled or controlled, and I cannot provide the assurances of confidentiality necessary to recruit participants.

17. This means that the work I am now in the midst of doing is immediately compromised by the Rule. Because of the Rule, I am immediately going to be limited in my ability to recruit new study participants, and unlikely to be able to recruit participants who are not documented, as I will need to disclose to them the likelihood that their information may be made public if the government relies on the results of my research. If I inform eligible individuals (and their families) that I cannot guarantee their confidentiality, they will not agree to participate in my study—especially if they are undocumented. As I noted earlier, my current research with the Fresno study cohort actually includes many undocumented cohort members, and the question of maintaining confidentiality from the government is of even more heightened concern to those individuals. And if, instead, I inform potential participants that the study will receive diminished weight in any EPA decision-making, they will be less likely to participate because they will see less value to the work.

18. To be clear—the problem is deeper than preserving personal identifiers and confidential personal information. In my experience, trust is essential to obtaining consent from individuals to participate in studies—especially among members of historically oppressed or disenfranchised communities, such as Latinx

community members and undocumented residents, many of whom are understandably wary about how information about them is used. Building that trust takes years of work and a proven history of meeting commitments. And it is delicate. Having to now go back to members of an existing cohort and tell them that the status and usefulness to the EPA of the research they participated in has changed, and/or that their personal information is at risk of being made public, immediately destroys that trust.

19. This means that the study that has been funded, and the researchers whose jobs depend in part on working on that study, are immediately compromised by the Rule. If we cannot replenish our study cohorts with sufficient numbers of new participants, we are in danger of losing our funding on which multiple jobs depend. We indicated in our successful R24 grant application for NIEHS funding that we had ~400 total participants in our Fresno study cohorts. That number of participants was criticized during the application review process as being small in size. If we lose more than 100 participants, NIEHS could consider our study population too small to merit continued funding. This means risks to nearly a dozen jobs: the Fresno children's study which I reference currently employs six faculty and staff at UCB and five staff at our field site at the Central California Asthma Collaborative.

20. The Rule also will adversely affect my work as a professor by discouraging me, my faculty colleagues, and students from engaging in this public

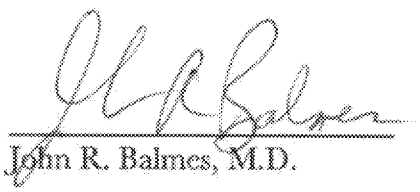
health research. To put a fine point on it, because the epidemiological studies I and my colleagues have built our careers on have just become less impactful in public policy decision-making, less likely to receive funding from federal and other agencies, and less interesting to the scientific community in general, students are less likely to want to pursue it. That also will mean that I—and other researchers across the country who do this work—will have a harder time securing funding to conduct air pollution epidemiological studies and attracting the best and brightest students to work in this important area of public health research. The best and brightest students and junior faculty will turn away from conducting air pollution epidemiological work and pursue other types of studies.

21. I also am deeply opposed to the Rule because it imposes artificial limitations on access to scientific information and how that information may be used. The validity of epidemiological studies does not depend on reviewing or having access to the underlying data, including confidential personal information of study participants. The Rule will not promote better decision-making or a better understanding of the environmental and health issues at stake. To the contrary, the Rule will limit decision-makers from being able to use the most valuable source of scientific information about the health effects of exposure to environmental toxicants: results of analyses of data from the individuals who actually are or have been exposed. With reduced access to that information, EPA decision-makers will

simply not be able to make fully informed decisions to protect the health and safety of at-risk populations.

I declare under the penalty of perjury that the foregoing is true and correct to the best of my knowledge and belief.

Dated: January 7, 2021



John R. Balmes, M.D.

# Exhibit A

OMB No. 0925-0001/0002 (Rev. 08/12 Approved Through 8/31/2015)

## BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: Balmes, John R., MD

eRA COMMONS USER NAME (credential, e.g., agency login): BALMES

POSITION TITLE: Professor, University of California, Berkeley and San Francisco

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

| INSTITUTION AND LOCATION | DEGREE *(if applicable)* | Completion Date MM/YYYY | FIELD OF STUDY |
|---|---|---|---|
| University of Illinois | BA | 06/1972 | Psychology |
| Mount Sinai School of Medicine | MD | 06/1976 | Medicine |
| Mount Sinai Medical Center, NYC | Residency | 06/1979 | Internal Medicine |
| Yale University | Post-doctoral fellowship | 06/1981 | Pulmonary Medicine |

**A. Personal Statement**

I am a physician-scientist who has been studying adverse health effects of air pollutants and other environmental toxins for over 40 years. I have investigated impacts of exposures to environmental agents on adults and children in both controlled human exposure and epidemiological studies. In my laboratory at the University of California, San Francisco, I have studied the acute effects of exposure to ozone, $SO_2$, $NO_2$, and particulate matter on lung function and airway inflammation in adults with asthma as well as cardiovascular effects of exposure to secondhand tobacco smoke and ozone. In Fresno, CA, I have studied the associations between air pollution and respiratory symptoms, lung function, and immune dysfunction in children with and without asthma. I was one of three multiple PIs leading a NIEHS/EPA-funded Children's Environmental Health Center (the Children's Health and Air Pollution Study or CHAPS); my project for CHAPS involved studying associations of exposure to air pollution with metabolic outcomes. Currently, I am the contact PI for an R24-funded 5-year extension of CHAPS. I have also participated in multiple studies of longitudinal change in lung function, several of which are noted below. I have a long-time collaborative relationship with both Drs. English and Solomon.

1. Pope D, Diaz E, Smith-Sivertsen T, Lie RT, Bakke P, **Balmes JR**, Smith KR, Bruce NG. Exposure to household air pollution from wood combustion and association with respiratory symptoms and lung function in nonsmoking women: results from the RESPIRE trial, Guatemala. Environ Health Perspect. 2015 Apr;123(4):285-92. PMCID: PMC4384202
2. Rylance S, Jewell C, Naunje A, Mbalume F, Chetwood JD, Nightingale R, Zurba L, Flitz G, Gordon SB, Lesosky M, **Balmes JR**, Mortimer K. Non-communicable respiratory disease and air pollution exposure in Malawi: a prospective cohort study. Thorax. 2020 Mar;75(3):220-226. PMCID: PMC7063402
3. Wilhelm M, Meng YY, Rull RP, English P, **Balmes J,** Ritz B. Environmental public health tracking of childhood asthma using California health interview survey, traffic, and outdoor air pollution data. Environ Health Perspect. 2008 Sep;116(9):1254-60. PMCID: PMC2535631
4. Reid CE, Mann JK, Alfasso R, English PB, King GC, Lincoln RA, Margolis HG, Rubado DJ, Sabato JE, West NL, Woods B, Navarro KM, **Balmes JR**. Evaluation of a heat vulnerability index on abnormally hot days: an environmental public health tracking study. Environ Health Perspect. 2012 May;120(5):715-20. PMCID: PMC3346770

**B. Positions and Honors**

1981-1982 Instructor in Medicine, Yale University
1983-1986 Assistant Professor of Medicine, University of Southern California
1986-1992 Assistant Professor of Medicine, University of California, SF
1992-1998 Associate Professor of Medicine, University of California, SF

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| 1998-present | Professor of Medicine, University of California, SF |
| 2002-present | Professor of Environmental Health Sciences, University of California, Berkeley |
| 1992-2014 | Chief, Division of Occupational and Environmental Medicine, SF General Hospital |
| 1988-2015 | Director, Human Exposure Laboratory, Lung Biology Center, UCSF |
| 2000-present | Director, Northern Calif. Center for Occupational and Environmental Health, UC Berkeley |
| 2014-present | Director, UC Berkeley-UCSF Joint Medical Program |
| 2008-present | Member, California Air Resources Board, Cal/EPA |

Pulmonary Academic Award, NHLBI, 1983-1986
Environmental/Occupational Medicine Academic Award, NIEHS, 1991-1996
Clean Air Research Award, American Lung Association of San Francisco and San Mateo, 1997
Clean Air Award, American Lung Association of California, 1999
Jean Spencer Felton Award for Excellence in Scientific Writing, Western Occupational and Environmental Medicine Association, 2002
Robert A. Kehoe Award of Merit, American College of Occupational and Environmental Medicine, 2006
Carl Moyer Award for Scientific Leadership and Technical Excellence, Coalition for Clean Air, 2006
Rutherford T. Johnstone Award for Exemplary Contributions to the Field of Occupational Medicine, Western Occupational and Environmental Medical Association, 2010
Robert M. Zweig Memorial Clean Air Hero Award, South Coast Air Quality Management District, 2012
Public Service Award in Recognition of Outstanding Contributions in Public Health in the area of Respiratory Disease and Medicine, American Thoracic Society, 2016
John M. Peters Award in Appreciation of a Lifetime of Leadership, Research, and Devoted Service to the Pursuit of Respiratory Health, American Thoracic Society Assembly on Environmental, Occupational and Population Health, 2016
Fellow, American Thoracic Society, 2018
Distinguished Achievement Award, American Thoracic Society, 2020

**C. Contributions to Science**

Controlled human exposure studies to ozone

My group was the first to demonstrate airway inflammation at the tissue level, increased airway inflammation in asthmatic subjects, an enhanced alveolar macrophage response after consecutive days of exposure, and heart rate variability after ozone exposure in experimental studies. These studies have provided important experimental support for the results of epidemiological studies that found associations between ambient ozone and exacerbations of asthma or cardiovascular mortality.

1. Arjomandi M, Witten A, Abbritti E, Reintjes K, Zhai W, Solomon C, **Balmes J**. Repeated exposure to ozone increases alveolar macrophage recruitment into asthmatic airways. Am J Respir Crit Care Med 2005;172:427-432. PMCID: PMC2718526
2. Arjomandi M, Wong H, Donde A, Frelinger J, Dalton S, Ching W, Power K, **Balmes J**. Exposure to medium and high ambient levels of ozone causes adverse systemic inflammatory and cardiac autonomic effects. Am J Physiol Heart Circ Physiol 2015; 308(12):H1499-509. PMCID: PMC446987
3. Arjomandi M, **Balmes JR**, Frampton MW, Bromberg P, Rich DQ, Stark P, Alexis NE, Costantini M, Hollenbeck-Pringle D, Dagincourt N, Hazucha MJ. Respiratory responses to ozone exposure. MOSES (The Multicenter Ozone Study in Older Subjects). Am J Respir Crit Care Med 2018;197:1319-1327. PMID: 29232153.

Epidemiological studies of the respiratory health effects of air pollution in children

I have collaborated on multiple research efforts to assess the relationships between exposure to various air pollutants and respiratory outcomes in children and adults. These studies include the growth of lung function, exacerbations of asthma, and incident asthma. The importance of these studies is that they provide evidence that real-world exposure to ambient pollutants is associated with respiratory morbidity.

1. Mortimer KM, Neugebauer R, Lurmann F, **Balmes JR**, Tager IB. The effect of prenatal and lifetime exposure to air pollution on the pulmonary function of asthmatic children. Epidemiology 2008;19:550-557. discussion 561-562.
2. Nadeau K, McDonald-Hyman C, **Noth EM**, Pratt B, Hammond SK, **Balmes J**, Tager I. Ambient air pollution impairs regulatory T-cell function in asthma. J Allergy Clin Immunol 2010;126:845-852. PMID: 20920773
3. Padula AM, **Balmes JR**, Eisen EA, Mann J, **Noth EM**, Lurmann FW, Pratt B, Tager IB, Nadeau K, Hammond SK. Ambient polycyclic aromatic hydrocarbons and pulmonary function in children. J Expo Sci Environ Epidemiol 2015;25:295-302. PMCID: PMC4270934.
4. Neophytou AM, White MJ, Oh SS, Thakur N, Galanter JM, Nishimura KK, Pino-Yanes M, Torgerson DG, Gignoux CR, Eng C, Nguyen EA, Hu D, Mak AC, Kumar R, Seibold MA, Davis A, Farber HJ, Meade K, Avila PC, Serebrisky D, Lenoir MA, Brigino-Buenaventura E, Rodriguez-Cintron W, Bibbins-Domingo K, Thyne SM, Williams LK, Sen S, Gilliland FD, Gauderman WJ, Rodriguez-Santana JR, Lurmann F, **Balmes JR**, Eisen EA, Burchard EG. Air pollution and lung function

in minority youth with asthma in the GALA II & SAGE II studies. Am J Respir Crit Care Med 2016;193(11):1271-1280. PMCID: PMC4910900.

Epidemiological and experimental studies of health effects of secondhand tobacco smoke

I have collaborated on the first studies to show acute cardiovascular effects of exposure to secondhand tobacco smoke (SHS). In addition, I have collaborated on several epidemiological studies of the impact of chronic exposures to SHS on COPD and cardiovascular mortality. The importance of the experimental studies is that they provide mechanistic evidence in support of the epidemiological data which demonstrate increased risk of COPD and cardiovascular mortality with exposure to SHS. Together this work supports legislative efforts to ban smoking in public places.

1. Eisner MD, Wang Y, Haight TJ, **Balmes J**, Hammond K, Tager IB. Secondhand smoke exposure, pulmonary function, and cardiovascular mortality. Ann Epidemiol 2007;17:364-373.
2. Heiss C, Amabile N, Lee AC, Real WM, Schick SF, Lao D, Wong ML, Sarah Jahn S, Angeli FS, Minasi P, Springer ML, Hammond SK, Glantz SA, Grossman W, **Balmes JR**, Yeghiazarians Y. Brief secondhand smoke exposure depresses EPC activity and endothelial function: sustained vascular injury and blunted NO production. J Am Coll Cardiol 2008;51:1760-1771.
3. Frey PF, Ganz P, Hsue PY, Benowitz NL, Glantz SA, **Balmes JR**, Schick SF. The exposure-dependent effects of aged secondhand smoke on endothelial function. J Am Coll Cardiol 2012; 59:1908-1913.

Epidemiological studies of the contribution of occupational exposures to the burden of COPD

I have collaborated on some of the key studies that have documented that 15-20% of the population attributable risk of chronic obstructive pulmonary disease is due to occupational exposures. This research is important because it identified the relative contribution of a preventable factor to a leading cause of death and disability world-wide.

1. Trupin L, Earnest G, San Pedro M, **Balmes JR**, Eisner MD, Yelin E, Katz PP, Blanc PD. The occupational burden of chronic obstructive pulmonary disease. Eur Respir J 2003; 22: 462-469.
2. Blanc P, Iribarren C, Trupin L, Earnest G, Katz P, **Balmes J**, Sidney S, Eisner M. Occupational exposures and the risk of COPD: dusty trades revisited. Thorax 2009;64:6-12. PMCID: PMC2775075

Epidemiological studies of adverse effects of household air pollution

I have collaborated on the first randomized controlled trial of a chimney stove for the prevention of early childhood pneumonia, written the grant that funded follow-up of the children's health later in childhood, and led several studies of adult respiratory outcomes. Household air pollution (HAP) is the leading environmental factor and 3rd most important factor overall contributing to the global burden of disease. This work has provided key data toward documenting the public health impact of this preventable environmental hazard.

1. Smith KR, McCracken JP, Weber MW, Hubbard A, Jenny A, Thompson LM, **Balmes J**, Diaz A, Arana B, Bruce N. Effect of reduction in household air pollution on childhood pneumonia in Guatemala (RESPIRE): a randomised controlled trial. Lancet 2011 Nov 12; 378(9804):1717-26.
2. Guarnieri MJ, Diaz JV, Basu C, Diaz A, Pope D, Smith KR, Smith-Sivertsen T, Bruce N, Solomon C, McCracken J, **Balmes JR**. Effects of woodsmoke exposure on airway inflammation in rural Guatemalan women. PLoS One 2014;9:e88455. PMCID: PMC3953023
3. Heinzerling AP, Guarnieri MJ, Mann JK, Diaz JV, Thompson LM, Diaz A, Bruce NG, Smith KR, **Balmes JR**. Lung function in woodsmoke-exposed Guatemalan children following a chimney stove intervention. Thorax 2016;71:421-428. PMID: 26966237.
4. *Mortimer K, Ndamala CB, Naunje A, Malava J, Katundu C, Weston W, Havens D, Pope D, Bruce N G, Nyirenda M, Wang D, Crampin A, Grigg J, **Balmes J**, Gordon S. A cleaner burning biomass-fueled cookstove intervention to prevent pneumonia in children under 5 years old in rural Malawi (CAPS): a cluster randomized controlled trial. Lancet 2016;389(10065):167–175. PMID: 27939058 PMCID: PMC5783287

*Best Environmental Epidemiology Paper of the Year Award – International Society for Environmental Epidemiology

**Complete List of Published Work in MyBibliography**:
http://www.ncbi.nlm.nih.gov/pubmed/?term=balmes+j

**D. Additional Information: Research Support and/or Scholastic Performance**

**Ongoing Research Support**

NIEHS R01ES029995 (Co-PIs: Clark, Volckens -- Colorado State Univ.; Balmes, Co-I) 11/1/2019-6/30/2024
Sustainable Household Energy Adoption in Rwanda [SHEAR]: Promoting Rural Health with Solar and Gas
The goal of this project is to conduct a randomized controlled trial of a combined clean cooking (LPG) and clean lighting (solar) household intervention to improve lung function and blood pressure.

NIEHS 1 R24 ES030888-01 (MPIs: Balmes, Holland, Noth) 2/15/2020-2/14/2025
CHAPS Cohort Maintenance
The major goal of this project is to continue longitudinal follow-up of the participants in the Children's Health and Air Pollution Study (CHAPS), an epidemiological study that has focused on the effects of air pollution on children growing up in the San Joaquin Valley of California, one of the most polluted areas in the country.

NIEHS 1 R21 ES030173-01A1 (Balmes) 4/01/2020-12/31/2021
AIMS to Improve Asthma: Airflow Improvements during Meal-prep in Richmond, CA
The major goal of this project is to study whether stove ventilation will reduce indoor fine particulate matter and improve asthma outcomes in a disadvantaged community.

**Recently Completed Research Support**

NIEHS/EPA P01 ES022849/83543501 (MPIs: Hammond, Shaw, Balmes) 7/17/2013-6/30/2019
UC Berkeley/Stanford Children's Environmental Health Center
This center is composed of four research projects examining the role of air pollution, especially ambient PAHs, on children's health, specifically in birth defects and prematurity, immunity and atopy mechanisms, obesity and glucose dysregulation.
Role: Multiple Principal Investigator

Enterprise Community Partners, Inc. 14-8623 (Balmes) 5/1/2014-4/30/2019
Healthy Homes, Healthy Kids
The major goal of this project is to study whether green renovation of public housing will improve asthma outcomes in children with asthma from disadvantaged families.
Role: Principal Investigator

NIEHS ES124362 (PI: Peel, Colorado State University) 7/1/2014-6/30/2019
Cookstove air pollution: emission profiles and subclinical effects of exposure
The major goal of this project is to perform subclinical cardiovascular and pulmonary tests of human volunteers exposed to emissions produced by several different cookstoves under controlled conditions.
Role: Co-investigator

Health Effects Institute (Balmes) 7/1/2011-6/30/2018
Multi-center Ozone Study in Elderly Subjects (MOSES)
The major goal of this project is to conduct controlled exposure studies of low levels of ozone to assess the risk of acute cardiovascular effects in older adults.
Role: Principal Investigator, UCSF site

NIEHS R56ES023566 (Balmes) 9/1/2014-8/31/2016
Cluster Randomized Controlled Trial of an Advanced Stove to Reduce Risk of COPD
The major goal is to study the efficacy of a relatively clean-burning biomass cook stove on respiratory symptoms and lung function in a cohort of women in multiple villages in rural Malawi.
Role: Principal Investigator

**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF MONTANA**
**GREAT FALLS DIVISION**

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| ENVIRONMENTAL DEFENSE FUND; MONTANA ENVIRONMENTAL INFORMATION CENTER; and CITIZENS FOR CLEAN ENERGY,<br><br>*Plaintiffs*,<br><br>v.<br><br>U.S. ENVIRONMENTAL PROTECTION AGENCY; and ANDREW R. WHEELER, in his official capacity as Administrator of the U.S. Environmental Protection Agency,<br><br>*Defendants*. | Case No.: 4:21-cv-00003-BMM-JTJ<br><br>The Honorable Brian Morris, Chief Judge |

**DECLARATION OF MARGARET KARAGAS, PHD**

I, Margaret Karagas, declare as follows:

1. My name is Margaret Karagas. I am the James W. Squires Professor and Chair of the Department of Epidemiology and Professor of Community and Family Medicine at Dartmouth Geisel School of Medicine in Hanover, New Hampshire. I also serve as the Director of the Children's Environmental Health and Disease Prevention Research Center and the Center for Molecular Epidemiology at

Dartmouth. I received my PhD from the University of Washington. I have authored or co-authored over 400 articles on a range of topics in epidemiology.

2. My research focuses on identifying emerging environmental exposures, host factors, and mechanisms that impact health from infancy to adult life, and applying novel methods and technologies to understand disease pathogenesis. My current research includes population-based studies of the increase in the incidence rates of keratinocyte cancers in the United States over time and the contribution of widespread exposures such as indoor tanning and drinking water contaminants. Through the Children's Environmental Health and Disease Prevention Research Center, I established a cohort of pregnant women and their offspring in New Hampshire to assess the sources and potential health impacts of arsenic and other factors on childhood infection, allergy/atopy, growth, and neurodevelopment. Research using this cohort will entail multiple collaborative studies of exposure biomarkers, individual susceptibility, and biological response to environmental agents including the developing microbiome and immune response.

3. I am a member of Environmental Defense Fund because I believe in its mission to advocate for science-informed policy and decision making, and to promote measures necessary to protect children, families, communities, and our planet.

4. I understand that the U.S. Environmental Protection Agency (EPA) has issued a rule entitled "Strengthening Transparency in Pivotal Science Underlying Significant Regulatory Actions and Influential Scientific Information" regarding how EPA may use studies examining "the quantitative relationship between the amount of dose or exposure to a pollutant, contaminant, or substance and an effect" on human health. *See* 86 Fed. Reg. 469, 470, 492 (Jan. 6, 2021) (codified at 40 C.F.R. § 30.2) (the "Rule"). This action establishes new restrictions on the ability of EPA to consider such dose-response data for which underlying data cannot be made "publicly available in a manner sufficient for independent validation." *Id.* at 492 (codified at 40 C.F.R. § 30.5(c)).

5. One of the main reasons I pursue my research is to improve health standards in order to lead to better health outcomes for people, particularly disadvantaged and at-risk communities. A critical motivating factor for pursuing particular lines of research is knowing that the results can contribute to new standards, particularly for chemicals and pollutants that are shown to contribute to poor health outcomes, and can receive full weight in decision-making regarding those standards. Because of EPA's regulatory authority over drinking water arsenic, nitrate and nitrites, disinfection byproducts and other contaminants, being able to make my work available to and usable by EPA is an important factor in designing and pursuing my research.

6. The nature of my work requires that I collect sensitive personal information about my study subjects. In addition to traditional personal identifiers such as name and address, I collect a wide range of deeply personal health behavior, demographic, socioeconomic, medical, and biometric data from study participants. These data are often collected from large study groups over many years. I believe the kinds of data my studies generate would be considered "dose-response data" as defined by the Rule.

7. A critical element in recruiting study subjects is my ability to promise that I can and will keep that information confidential, and that published data is "de-identified;" that is, detached from information like name and address that could link the published data to sensitive personal health or medical data from any specific individual. We have participants sign consent forms based on our promise to keep their data confidential. In addition, professional ethical standards and legal requirements further require that personal data be kept confidential. The specific and detailed procedures to protect confidentiality are set forth in the conditions required by university institutional review boards and as conditions of grants from the National Institutes of Health (NIH) and other grant-giving entities.

8. I understand that the Rule contemplates mechanisms for researchers to make data available "through restricted access in a manner sufficient for independent validation." *See* 86 Fed. Reg. 492 (codified at 40 C.F.R. § 30.5(c)). I am

not aware of any such methods that would comply with the confidentiality agreements I reach with my research subjects. This would entail seeking IRB approval can be burdensome, and if an IRB would to agree to such terms, it would take a prohibitive amount of time and resources to re-consent participants.

9. If I could not promise to keep personal data confidential in order to preserve my ability to make my study results available to—and fully considered by—EPA, I would not be able to meet my ethical and legal obligations and the quality of my research would suffer.

10. With respect to ongoing studies, I would need to seek the consent of current participants and seek approval from the appropriate institutional review boards in order to change my protocol and make confidential information publicly available—or sharable with EPA in any form—as the Rule would require for that research to receive full weight as pivotal science. I would expect a large number of participants to drop out of the study, making its results less reliable and less useful. I would also expect institutional review boards to not approve those kinds of changes due to existing legal and ethical obligations.

11. And with respect to new studies, without the promise of confidentiality it would be very difficult, if not impossible, to recruit participants. Even if I were able to recruit some participants, they would likely be fewer in number and constitute an unrepresentative sample. As a consequence, the quality and usefulness of the

research would be compromised. My research is typically based on studying large studies of the general population of the US. A small and unrepresentative study sample makes the results less relevant to the overall population and therefore less meaningful, and less useful to regulators like EPA who impose national standards.

12. These problems would make it extremely difficult to obtain funding and approval for my research. It is highly unlikely that my research would be approved by my University, the NIH, or other grant-giving entities if I could not preserve participant confidentiality or if I could not produce reliable data.

13. But if I did not adjust my research agenda to produce work that could be accorded full weight by EPA, I am still concerned that I would be unable to obtain funding. I know that an important factor in awarding NIH grants is the ability of research to have an impact on government policies and standards. If my research cannot be used to affect decision-making by EPA, NIH is less likely to fund research relevant to pollutants and substances regulated by EPA. Almost all of my research is funded through external grants coming from NIH. For example, in 2020 100% of my external funding for research I lead or jointly lead with other scientists came from NIH grants, which comprised over 95% of the total research that I lead.

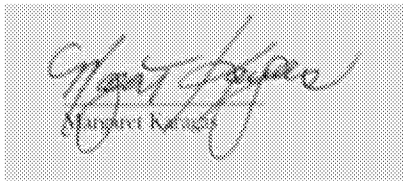
14. Without NIH funding, I would not be able to carry out most of my research and the jobs of my colleagues and staff who work on NIH-funded grants

would be at risk. This currently includes 37 staff members and learners and 19 faculty members.

15. Fundamentally, I do the research I do to inform policy and improve public health. If I knew that the results of my research could not be used by EPA to make decisions to improve public health policy and lead to better health outcomes for individuals—or could not receive full weight in those decisions—there would be no reason to do that work and I would change my research priorities and/or methodologies to areas where there would not be similar impediments to my research's having an impact on improving public health policy and decisions. Adjusting my research priorities or methodologies would require me to devote time and resources to devising new methods and research priorities rather than pursuing my current research. Epidemiologic studies often take years to acquire the necessary information and measurements and to follow participants to observe their health outcomes. We have invested decades of time and money to collect valuable data to be able to address critical public health issues including emerging drinking water contaminants, air pollutants and other concerns. To switch gears at this stage would mean the impacts of my research would be significantly diminished at a time when I have the most to offer.

I declare under the penalty of perjury that the foregoing is true and correct to the best of my knowledge and belief.

Dated: January 8, 2021



**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF MONTANA**
**GREAT FALLS DIVISION**

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| ENVIRONMENTAL DEFENSE FUND; MONTANA ENVIRONMENTAL INFORMATION CENTER; and CITIZENS FOR CLEAN ENERGY,<br><br>*Plaintiffs*,<br><br>v.<br><br>U.S. ENVIRONMENTAL PROTECTION AGENCY; and ANDREW R. WHEELER, in his official capacity as Administrator of the U.S. Environmental Protection Agency,<br><br>*Defendants*. | Case No.: 4:21-cv-00003-BMM-JTJ<br><br>The Honorable Brian Morris, Chief Judge |

**DECLARATION OF BENJAMIN M. LEVITAN**

I, Benjamin M. Levitan, declare as follows:

1. I am a Senior Attorney on the U.S. Clean Air team at Environmental Defense Fund ("EDF"). I have been employed by EDF continuously for more than five years.

2. I am submitting this declaration in support of EDF's Administrative Procedure Act action asking this Court to hold unlawful and set aside the U.S. Environmental Protection Agency's ("EPA") decision to make the rule

"Strengthening Transparency in Pivotal Science Underlying Significant Regulatory Actions and Influential Scientific Information" (the "Rule") effective immediately upon publication in the Federal Register and to declare that the Rule will not become effective for at least 30 days from the date of publication.

3. I am responsible for overseeing and otherwise supporting certain of EDF's legal and advocacy activities, including activities relating to EDF's advocacy for clean-air protections and scientific integrity at EPA.

4. EDF's mission is to preserve the natural systems upon which all life depends by using science, economics, and the law to find practical and lasting solutions to the most serious environmental problems. A core aspect of this work is presenting information to government decision-makers responsible for issuing public health and environmental protections to address the risk that exposure to pollution and chemicals inflicts upon public health and the environment.

5. EDF routinely presents scientific information about the risks of pollution and chemicals to EPA, including studies relying on "dose-response data," and it is essential to our work that EPA be able to rely on that information for all of its regulatory actions. But by impairing EPA's ability to consider or give due weight to scientific findings presented by EDF, the Rule thwarts EDF's mission to use science to inform government decision-makers about environmental and public health risks created by pollution and chemicals.

6. I have been actively involved in EDF's efforts to oppose EPA's promulgation of the Rule, which EDF believes unlawfully and harmfully restricts EPA's consideration of vital, rigorous scientific studies when setting public health and environmental protections. EDF's principal efforts to oppose the Rule include:

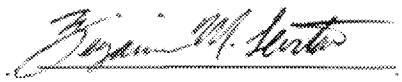
- On March 20, 2018, EDF submitted a Freedom of Information Act ("FOIA") request to EPA for public records related to the development of the proposed Rule.
- On May 4, 2018, following the release of EPA's proposed Rule, EDF submitted a second FOIA request to EPA for records related to the development of the proposed Rule.
- On July 17, 2018, two EDF staff spoke at EPA's public hearing on the proposed Rule to convey EDF's opposition.
- On August 7, 2018, EDF filed suit against EPA for failing to respond to the two FOIA requests described above in accordance with statutory requirements.
- On August 16, 2018, EDF submitted a 193-page comment, as well as numerous attachments, opposing the first iteration of the proposed Rule.
- On May 18, 2020, EDF submitted a 94-page comment, as well as numerous attachments, opposing the supplemental notice of proposed rulemaking for the Rule.
- EDF met with staff of the White House Office of Management and Budget to discuss the proposed Rule on November 22, 2019, and again to discuss the final Rule on September 28, 2020.

7. Because of its concerns about the Rule, EDF had intended to exercise its right to request that EPA administratively postpone the effective date of the Rule under Section 705 of the Administrative Procedure Act. By deeming the Rule effective immediately upon publication in the Federal Register, EPA abrogated EDF's right to seek a stay under Section 705 of the Administrative Procedure Act.

8. If the Court sets aside EPA's decision to make the Rule effective immediately, EDF will promptly seek a Section 705 stay. If the Court does not grant the requested relief, however, EPA will be unable to grant such a stay—and the Rule will remain in effect—even though EPA may have granted the stay if it had been given an opportunity to do so. As a result, EDF and its members will lose an opportunity they otherwise would have had to avoid the Rule's serious consequences for their mission and well-being.

9. As described above, the Rule also compromises EDF's mission to develop, utilize, and rely upon rigorous scientific studies in order to inform EPA about the need to implement public health and environmental protections. EDF suffers that harm at any point that the Rule is in effect.

Dated: January 8, 2021



Benjamin M. Levitan

**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF MONTANA**
**GREAT FALLS DIVISION**

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| ENVIRONMENTAL DEFENSE FUND; MONTANA ENVIRONMENTAL INFORMATION CENTER; and CITIZENS FOR CLEAN ENERGY,<br><br>*Plaintiffs*,<br><br>v.<br><br>U.S. ENVIRONMENTAL PROTECTION AGENCY; and ANDREW R. WHEELER, in his official capacity as Administrator of the U.S. Environmental Protection Agency,<br><br>*Defendants*. | Case No.: 4:21-cv-00003-BMM-JTJ<br><br>The Honorable Brian Morris, Chief Judge |

**DECLARATION OF JOHN STITH**

I, John Stith, declare as follows:

1. I am Director of Database Marketing and Analytics at Environmental Defense Fund (EDF).

2. My duties include maintaining an accurate list of members. My colleagues and I provide information to members, acknowledge gifts and volunteer actions, and manage the organization's member databases. My work requires me to be familiar with Environmental Defense Fund's purposes, staffing, activities, and

membership. I have worked at EDF and overseen the membership databases for over fourteen years.

3. Environmental Defense Fund is a membership organization incorporated under the laws of the State of New York. It is recognized as a not-for-profit corporation under section 501(c)(3) of the United States Internal Revenue Code.

4. Environmental Defense Fund relies on science, economics, and law to protect and restore the quality of our air, water, and other natural resources. Environmental Defense Fund employs more than 700 scientists, economists, engineers, business school graduates, lawyers, and other professionals to help solve challenging environmental problems in a scientifically sound and cost-effective way.

5. Through its programs aimed at protecting human health and the environment, Environmental Defense Fund has long pursued initiatives at the state and national levels designed to reduce air pollution and protect public health. This work addresses emissions of greenhouse gases, air pollutants classified as "hazardous air pollutants" under the Clean Air Act, and other harmful air pollutants such as criteria air pollutants through the National Ambient Air Quality Standards. It also includes strengthening protections under the Safe Drinking Water Act, Toxic Substances Control Act, and other laws to reduce public exposure to pollutants harmful to human health. For example, EDF works to reduce lead in drinking water,

lessen harmful chemicals in food, and get toxic chemicals out of household products. Ensuring the best available science, economics, and analysis inform these and other public health and environmental protections is at the core of EDF's mission and values. Because scientific evidence is central to informing policy decisions for the protection of the environment and public health, EDF relies on the best scientific evidence—including studies that directly assess the health outcomes from exposure to pollutants—to support regulations that are robustly protective of public health and the environment. These efforts include providing such evidence to EPA and other decisionmakers.

6. Collaboration with other organizations, businesses, and government is a core part of EDF's strategy to reduce air pollution and protect public health. EDF works closely with many partners addressing environmental justice issues. These partners work in communities that disproportionately bear the burdens of pollution and other environmental and health impacts. EDF and its partners have worked diligently to build trust in these communities to help address and alleviate the environmental and health harms they face.

7. EDF has a strong organizational interest, as well as a strong interest grounded in its members' recreational, aesthetic, professional, educational, public health, environmental, and economic interests, in advancing protections of public health, the environment, clean air, and the climate system. These interests extend to

ensuring the best scientific evidence receives due weight in the setting of robust policies that are adequately protective of public health and the environment. EPA science prioritization policies that hinder scientists from obtaining the grants necessary to conduct their research or otherwise maintain their labs and projects, or that cause scientists to conduct less scientifically valuable research, would threaten this interest. EDF also counts among its members scientists whose professional and economic interests would be harmed by such policies. EDF also has a strong interest in leveraging the work of its partners and ensuring that its partners, particularly those that work in environmental justice communities, can develop actionable data and the best science to help address and alleviate the environmental and health harms such communities experience.

8. When an individual becomes a member of Environmental Defense Fund, his or her current residential address is recorded in our membership database. The database entry reflecting the member's residential address is verified or updated as needed. The database is maintained in the regular course of business and each entry reflecting a member's residential address and membership status is promptly updated to reflect changes.

9. As of January 4, 2021, Environmental Defense Fund has 397,459 members in the United States, and we have members in all 50 states and the District of Columbia. As of January 6, 2021, Environmental Defense Fund has 1,686 members

in Montana. EDF members have a strong interest in protecting human health and the environment, including from air pollution and other toxic exposures. Many live in areas affected by hazardous air pollution, including those whose local water bodies are subject to fish consumption advisories due in part to mercury pollution from power plants that bioaccumulates in fish populations and makes the fish unsafe to eat in significant amounts. Others live in areas with ozone and particulate matter pollution levels above what the latest science suggests can be harmful. These pollutants cause an increased risk of asthma attacks, heart attacks, strokes, emergency room visits, and premature deaths. Members across the country, including in Montana, rely on the latest regulations to protect them from harmful exposures in the water they drink, food they eat, and household products they use regularly. Members' well-being depends on EPA's maintaining and strengthening health-protective standards as necessary to keep up with the best available science.

10. For over 40 years, EDF has worked to protect human health and the environment from air pollution in Montana through the advocacy of its long-standing Rocky Mountain Office, its affiliation with Moms Clean Air Force representatives in Montana, expert consultants, and its work with partners such as the Montana Environmental Information Center. EDF's efforts include national, regional, and state-based legal and policy advocacy to address adverse health and other environmental impacts in Montana due to deadly particulate pollution, smog-

forming contaminants, mercury and other air toxics, climate pollution and an array of air pollution from industrial sources including power plants, and oil and gas activities.

11. After EPA released the proposed "Strengthening Transparency in Regulatory Science" Rule, 83 Fed. Reg. 18,768 (Apr. 30, 2018), 60,000 EDF members and supporters, including 279 commenters from Montana, submitted comments opposing the proposed rule. When EPA published an associated supplemental notice of proposed rulemaking, *see* 85 Fed. Reg. 15,396 (Mar. 18, 2020), almost 80,000 EDF members and supporters, including 303 commenters from Montana, submitted comments in opposition. EDF staff also submitted technical comments opposing the proposed rule and the associated supplemental notice of proposed rulemaking.

12. If in effect, the "Strengthening Transparency in Pivotal Science Underlying Significant Regulatory Actions and Influential Scientific Information," Rule, 86 Fed. Reg. 469 (Jan. 6, 2021), would jeopardize the protections EDF members living all over the United States rely upon to limit their exposure to air pollution and other harmful exposures linked to serious human health impacts.

I declare under the penalty of perjury that the foregoing is true and correct.

Dated: January 10, 2021

John Stith

**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF MONTANA**
**GREAT FALLS DIVISION**

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| ENVIRONMENTAL DEFENSE FUND; MONTANA ENVIRONMENTAL INFORMATION CENTER; and CITIZENS FOR CLEAN ENERGY,<br><br>*Plaintiffs*,<br><br>v.<br><br>U.S. ENVIRONMENTAL PROTECTION AGENCY; and ANDREW R. WHEELER, in his official capacity as Administrator of the U.S. Environmental Protection Agency,<br><br>*Defendants*. | Case No.: 4:21-cv-00003-BMM-JTJ<br><br>The Honorable Brian Morris, Chief Judge |

**DECLARATION OF DR. JENNIFER MCPARTLAND**

I, Dr. Jennifer McPartland, declare as follows:

1. I, Dr. Jennifer McPartland, am a Senior Scientist in the Health program at Environmental Defense Fund ("EDF"). I have held this position for over 10 years. I received my doctorate degree in microbiology in 2008 from the University of Chicago and then pursued further post-doctoral research there. The research I conducted over this period of time spanned the fields of microbiology and molecular biology. I received a Bachelor of Science in chemistry with a specialization in biochemistry from the University of Virginia in 2003.

2. At EDF, I focus on advancing science, policy, and market solutions to protect human health and the environment from harmful chemical exposures. I lead EDF's engagement in federal efforts to advance and appropriately apply new chemical testing approaches and systematic review practices in chemical hazard, exposure, and risk assessments. I also support EDF's efforts to ensure health-protective implementation of the Toxic Substances Control Act ("TSCA"), the nation's main chemical safety law, by working to build strong chemical review and risk management processes at the U.S. Environmental Protection Agency ("EPA" or "agency").

3. I currently serve on the Environmental Health Matters Initiative Committee of the National Academies of Sciences, Engineering, and Medicine, the EPA's Board of Scientific Counselors Chemical Safety for Sustainability Subcommittee, and the GreenScreen for Safer Chemicals Science Advisory Committee.

4. I am familiar with the new EPA rule "Strengthening Transparency in Pivotal Science Underlying Significant Regulatory Actions and Influential Scientific Information" published in the Federal Register on January 6, 2021, which addresses whether and how EPA may consider or rely upon studies which assess "the quantitative relationship between the amount of dose or exposure to a pollutant, contaminant, or substance and an effect" on health in setting standards or taking

other significant regulatory actions or developing "influential scientific information." *See* 86 Fed. Reg. 469, 470 (Jan. 6, 2021) ("Rule"). The Rule significantly restricts EPA's ability to consider such dose-response studies for which underlying data are not "publicly available in a manner sufficient for independent validation." 86 Fed. Reg. at 492.

5. The Rule would limit EPA's consideration of many important dose-response studies, including those that contain personal information about study participants that cannot be legally or ethically disclosed, even though such studies have been rigorously vetted using time-tested approaches that are widely accepted in the scientific community. Legal and ethical requirements and other barriers that restrict the ability to make public the data underlying these studies include requirements to shield private personal information and situations where obtaining the necessary permissions to release data is logistically difficult or impossible. Even when there are potential ways to address some of these barriers, doing so can be extremely costly and burdensome to the point of infeasibility, and/or may harm researchers' prospects for further research.

## SECTION I: EDF'S USE OF STUDIES IMPACTED BY THE RULE IN OUR ADVOCACY

6. Under TSCA, EPA is required to assess potential risks from new and existing chemicals and address any unreasonable risks chemicals may pose to human health or the environment. For existing chemicals, this generally proceeds through

a three-step process. *First*, EPA designates specific chemicals as either "high priority" or "low priority." *Second*, for those chemicals designated high priority, EPA conducts risk evaluations to determine whether the chemicals pose an "unreasonable risk." As part of the risk evaluation process, EPA is required to publish a draft scope, final scope, draft risk evaluation, and final risk evaluation. *Third*, if EPA determines that a chemical poses any unreasonable risk, TSCA requires the agency to promulgate a risk management rule sufficient to eliminate the unreasonable risk. EPA allows for public comment on the chemical prioritization, assessment, and management stages of the process, and EDF actively participates in the public comment process.

7. I have long been involved in EDF's efforts to ensure that chemicals are comprehensively assessed and regulated under TSCA where warranted to protect public health using the best available science. As one recent example, EDF submitted comments on EPA's risk evaluation of trichloroethylene ("TCE"). I was directly involved in the development and writing of these comments. In our comments, EDF relied on several studies that demonstrate an association between TCE exposure and congenital heart defects, and identified such defects as the most sensitive human health effect of TCE exposure. A deep flaw in the draft and final risk evaluations of TCE was EPA's reliance on immune-related endpoints instead of congenital heart defects for its determinations of acute and chronic risks of TCE exposure. EPA's decision not to use the most sensitive endpoint for making

determinations of TCE's risks deviates from scientific best practices, defies requirements under TSCA, ignores longstanding agency policy, and is not sufficiently protective of the health of the public and vulnerable subpopulations. EDF's comments focused significantly on this fundamental flaw, highlighting studies in the scientific literature supporting identification of congenital heart defects linked to TCE exposure. If the Rule were in place, EPA would be constrained in considering EDF's comments because the data underlying a number of the dose-response studies we cited in our comments are not publicly available.

8. EPA issued a final risk evaluation for TCE on November 24, 2020[1] and is now developing a risk management rule to address unreasonable risks it identified in the risk evaluation. Under TSCA, EPA must propose the risk management rule within one year and finalize that rule within two years of the date on which it issued the final risk evaluation. EDF expects to review and comment on the proposed risk management rule. As support for our comments on the proposed risk management rule, I expect to rely on and cite a number of dose-response studies.

9. The data underlying some of the key dose-response studies we expect to reference in our comments are not publicly available for a variety of reasons.[2] I

[1] 85 Fed. Reg. 75,010 (Nov. 24, 2020).

[2] Examples of dose-response studies we plan to cite and that do not have publicly available underlying data include:

expect that making the data available through restricted access would frequently be impossible or infeasible due to logistical, financial, legal, ethical, or other constraints. As a result, EPA could choose to ignore or give less consideration to comments from EDF on the proposed risk management rule that rely on these critical studies. Restraints on EPA's ability to rely on certain dose-response studies significantly hampers the effectiveness of EDF's comments identifying the scientific flaws with EPA's current approach.

10. As another example, through a multi-step process, EPA has identified 20 additional chemicals which will undergo risk evaluations under TSCA. Each of these chemicals was designated "high priority" under procedures defined in EPA rules—procedures which involve public comment. EPA also recently took comment on draft scopes of the risk evaluations for each of these 20 substances.

11. EDF submitted comments throughout this multi-step process. In our comments on the high-priority designation of one of these 20 chemicals, formaldehyde, and on the scope of its risk evaluation, we noted that formaldehyde is

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- Paula D. Johnson et al., *Threshold of Trichloroethylene Contamination in Maternal Drinking Waters Affecting Fetal Heart Development in the Rat*, 111 Envtl. Health Persp. 289 (2003).
- Patricia T. Caldwell et al., *Gene expression profiling in the fetal cardiac tissue after folate and low-dose trichloroethylene exposure*, 88 Birth Defects Research Part A: Clinical and Molecular Teratology 111, 111–27 (2010).
- Steven P. Forand et al., *Adverse Birth Outcomes and Maternal Exposure to Trichloroethylene and Tetrachloroethylene through Soil Vapor Intrusion in New York State*, 120 Envtl. Health Persp. 616 (2012).

a known human carcinogen associated with nasopharyngeal cancer and leukemia. We relied on a number of dose-response studies in our comments on the proposed high-priority designation and on the draft scope of the risk evaluation of this chemical.[3]

12. EDF anticipates that EPA's draft risk evaluation of formaldehyde will be released in 2021.[4] EDF intends to submit comments on that draft risk evaluation that we expect will again refer to these and other dose-response studies. In assessing and commenting on the draft risk evaluation, EDF will rely on such studies to determine whether the risk evaluation sufficiently considers the body of evidence regarding potential effects of exposure to formaldehyde.

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[3] Examples of formaldehyde dose-response studies that we relied on in our comments include:

- M. Hauptmann et al., *Mortality from Solid Cancers Among Workers in Formaldehyde Industries*, 159 Am. J. Epidemiology 1117 (2004).
- Allan Hildesheim et al., *Occupational Exposure to Wood, Formaldehyde, and Solvents and Risk of Nasopharyngeal Carcinoma*, 10 Cancer Epidemiology, Biomarkers & Prevention 1145 (2001).
- Thomas L. Vaughan et al., *Occupational Exposure to Formaldehyde and Wood Dust and Nasopharyngeal Carcinoma*, 57 Occupational & Envtl. Med. 376 (2000).
- Sheila West et al., *Non-viral Risk Factors for Nasopharyngeal Carcinoma in the Philippines: Results from a Case-Control Study*, 55 Int'l J. Cancer 722 (1993).

[4] EPA identified these chemicals as high priority in December 2019, and its final risk evaluations are due 3 years after that (December 2022), subject to a six-month extension. EPA must publish draft risk evaluations for public comment and peer review with adequate time to permit the agency to meet the three-year statutory deadline.

13. The effectiveness of EDF's reliance on and presentation of these studies in our comments to EPA would be adversely impacted by the Rule because data underlying many if not most of these studies are not publicly available, and I do not expect that all the associated the data would be available via restricted access.

14. EDF also commented on the draft scopes for six phthalates that are among the 20 high-priority chemicals currently undergoing risk evaluation. We expect to comment on further EPA actions, including the draft risk evaluations EPA issues for these substances. In our comments on the draft scopes for the phthalates, we noted the links between exposure to certain phthalates and adverse health effects. In research we conducted on these chemicals, we have located dose-response studies that identify adverse health impacts.[5]

15. I anticipate that we will rely on these studies to comment on EPA's draft risk evaluation once it is released (likely in 2021). However, the effectiveness of our comments that rely on these studies will be limited by the Rule because the underlying data is not publicly available for some of them.

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[5] Examples of phthalate dose-response studies include:

- Robin M. Whyatt et al., *Asthma in Inner-City Children at 5–11 Years of Age and Prenatal Exposure to Phthalates: The Columbia Center for Children's Environmental Health Cohort*, 122 Envtl. Health Persp. 1141 (2014).
- Pam Factor-Litvak et al., *Persistent Associations between Maternal Prenatal Exposure to Phthalates on Child IQ at Age 7 Years*, PLOS ONE 9(12) (2014).

16. In each of the circumstances described above, the Rule will impede EDF's and my ability to provide influential and effective comments to EPA on various documents published by EPA under TSCA (*e.g.*, draft scopes, draft risk evaluations, proposed risk management rules) because the Rule restricts EPA's ability to consider our comments that rely on dose-response studies whose underlying data are not publicly available. This will limit our ability to provide the most compelling, scientifically informed, and accurate information to the agency, as well as our ability to advocate effectively for public health protections. For example, if comments we submit to EPA are ignored or given less weight because the data underlying studies we rely on in those comments are not publicly available or available via restricted access, we would be prevented from making the most compelling argument that science has established a relationship between formaldehyde exposure and adverse effects including leukemia.

**SECTION II: BURDENS OF COMPLYING WITH THE RULE**

17. Based on my understanding of the Rule, EPA will be limited in its ability to fully consider nearly any dose-response study for which the underlying data are not publicly available (or available via restricted access), which, in turn, stymies advocates, including EDF and myself, from effectively utilizing that type of scientific information in our advocacy before the agency. In the realm of public health, which EPA is charged with protecting, dose-response studies provide critical scientific

information to inform the development of chemical assessments, regulations, and other types of documents and actions EPA is statutorily required to develop and undertake.

18. The Rule will increase the burden on scientists, including myself, who rely on scientific studies to advocate and comment on EPA actions, processes, and assessments. In order to be confident that our comments can serve their intended purpose of informing EPA activities and decision-making, we will have to ensure that studies we rely on in our advocacy comply with the Rule.

19. This effort will be enormously burdensome. For a given TSCA comment, the studies that I reference may number in the hundreds. It already takes me a substantial amount of time to identify such studies and use them to prepare such a comment. To ensure that that work can serve its intended purpose—to actually be fully considered by EPA—I will need to assess every relevant study upon which we might rely to determine whether it uses data that are or could be made publicly available by the study's author(s). This will require me to engage in a complicated and involved process, including: determining what studies the Rule applies to; for those studies to which it does apply, researching whether the data are publicly available; when I cannot find the data in a publicly accessible platform, contacting and asking the study authors if the data are publicly available or could be made publicly available or available through restricted access; and, if not—even

assuming that the author or data owner is able or willing to engage with me—discussing with authors about the release of the data (including examining legal, ethical, and logistical constraints, the need to obtain consent from all study participants—which may be prohibitive—the logistics and expense of releasing the data, and more). Alternatively, I would need to devote considerable effort building a case as to why EPA should consider the studies even if the underlying data are not public. Because the Rule appears to require a study-by-study assessment, that effort would require substantial work for each study we intend to include in our comments. This will not only be unnecessarily labor intensive, but because of time and resource constraints I face in this work, I may well not be able to identify and include all relevant studies—which may well mean that I do not include some studies that are the best available science on a particular topic.

20. I will face these challenges immediately, such as with respect to comments I anticipate preparing on forthcoming TSCA draft risk evaluations and proposed risk management rules.

21. Moreover, I understand that the Rule has allowances for studies to be given lesser weight if their underlying data are not publicly available (or available via restricted access). Not only is this approach scientifically inappropriate—as the value, importance, rigor, or relevance of studies does not hinge on whether all of the underlying data are publicly available—but it will do little to reduce the burden the

Rule imposes on advocates and scientists like me. Because we will be unsure as to the weight EPA will give to a particular study, we will still need to evaluate the availability of underlying data in order to improve the prospects that the studies we include will receive at least some weight.

22. Although EPA has suggested that not *all* studies provided in a given assessment or process would necessarily be treated as "pivotal science," it has not sufficiently defined the parameters it will use to determine which studies qualify as pivotal science to reduce the burden I anticipate. If the Rule may (or may not) limit the ability of the agency to consider any and all studies which may inform a particular "significant regulatory action" or piece of "influential scientific information," advocates and scientists, including me, will still have to investigate each study upon which we rely to determine if it would meet the Rule's requirements. For example, I could submit or rely upon dose-response studies in commenting on a draft risk evaluation under TSCA (which is influential scientific information) under the impression that they would not be impacted by the Rule, only to have our comments and arguments given less weight if the agency decides that the studies are, in fact, "pivotal science." Or, conversely, to try to mitigate the risk that our comment could be given less weight, I could expend serious resources investigating the studies upon which I would like to rely (or be concerned that EPA will give less weight to certain

studies if they do not meet the Rule's requirements)—only to learn that they are not impacted by the Rule.

## CONCLUSION

23. I am certain that the Rule will negatively affect my ability to effectively advocate for stronger public health protections under TSCA. The Rule will limit my ability to have any confidence that EPA will give any or sufficient weight to comments in which I rely on some of the best (or only) available science to demonstrate an association between a chemical and certain health impacts if the underlying data are not or cannot be made publicly available, due to legal, ethical, logistical or other constraints. In addition, the Rule will impose substantial burdens on me and my colleagues who use peer-reviewed science to advocate for public health protections if we do wish to use certain studies in our comments and other advocacy to the agency. We will have to investigate whether the data underlying each such study are publicly available; if they are not (which I anticipate will be the case for many or most studies), we will have to attempt to convince study authors to make the data available in a manner that satisfies the Rule. Even if the author or data owner agrees to try to do so, there may very well be substantial legal, ethical, logistical, and other barriers. Engaging in any of the foregoing processes will consume considerably more time and resources than previously were required. In

this manner, the Rule will substantially harm my and EDF's ability to effectively advocate for public health protections in a scientifically rigorous manner.

I declare under the penalty of perjury that the foregoing is true and correct to the best of my knowledge and belief.

Dated: January 10, 2021

Jennifer McPartland

**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF MONTANA**
**GREAT FALLS DIVISION**

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| ENVIRONMENTAL DEFENSE FUND; MONTANA ENVIRONMENTAL INFORMATION CENTER; and CITIZENS FOR CLEAN ENERGY,<br><br>*Plaintiffs*,<br><br>v.<br><br>U.S. ENVIRONMENTAL PROTECTION AGENCY; and ANDREW R. WHEELER, in his official capacity as Administrator of the U.S. Environmental Protection Agency,<br><br>*Defendants*. | Case No.: 4:21-cv-00003-BMM-JTJ<br><br>The Honorable Brian Morris, Chief Judge |

**DECLARATION OF RICHARD D. LIEBERT**

I, Richard D. Liebert, declare as follows:

1. I am the President of Citizens for Clean Energy, Inc. and the Chair of its Steering Team.

2. Citizens for Clean Energy (CCE) is nonprofit organization of Montana citizens whose objective is to convince decisionmakers to adopt clean energy solutions in order to preserve Montanans' health, lifestyle, and heritage and to protect Montana's land, air, water, and communities from the consequences of fossil fuel development, including the pollution and chemical effects of Montana's coal

industry. CCE is based in Great Falls, Montana and has members throughout the state.

3. As part of this mission, CCE aims to ensure that federal officials, including the U.S. Environmental Protection Agency (EPA), comply with and fully uphold the laws of the United States that are designed to protect Montana communities and the environment from the pollution and chemical effects of fossil fuel development. Its work includes advocacy to reduce the use and impacts of dirty coal production and waste, advocacy CCE backs up with the best available science. CCE works to protect Montanans and our fundamental right to a clean and healthful environment under Montana's Constitution.

4. This effort includes participating in EPA rulemakings and, when necessary, engaging in litigation against EPA to ensure that it protects the interests of CCE and its members, both of which depend on CCE's ability to rely on the best available science and to ensure that EPA accord this science full weight in its decision-making. CCE believes that fully informed scientific decision-making is critical in order to reach good decisions that affect human health and our environment.

5. CCE brings this action on its own behalf and on behalf of its members.

6. CCE members have intensive, long-standing recreational, aesthetic, scientific, professional, and spiritual interests in the responsible production and use

of energy and the land, air, water, and communities impacted by fossil fuel development.

7. I am familiar with the new EPA rule "Strengthening Transparency in Pivotal Science Underlying Significant Regulatory Actions and Influential Scientific Information" published in the Federal Register on January 6, 2021, which addresses how EPA may consider or rely upon studies that assess "the quantitative relationship between the amount of dose or exposure to a pollutant, contaminant, or substance and an effect" on human health in setting standards or developing "influential scientific information." 86 Fed. Reg. 469, 470, 492 (Jan. 6, 2021) (codified at 40 C.F.R. § 30.2) (the "Rule"). The Rule limits EPA's ability to consider such "dose-response data" for which the underlying data cannot be made "publicly available in a manner sufficient for independent validation." *Id.* at 492 (codified at 40 C.F.R. § 30.5(c)). In practice, that would mean many studies of the impacts of pollution and chemicals on human health—just the sorts of studies on which CCE advocacy depends—would receive less weight in EPA decision-making. It is my understanding that many of these studies are based on confidential subject information that cannot be made publicly available under the conditions imposed by universities, Institutional Review Boards, and agreements with participants.

8. The Rule will have immediate consequences for CCE. It will now be more difficult, and more expensive, for us to incorporate the best scientific evidence

into our advocacy before EPA. We will now need to begin any federal advocacy with figuring out the implications of the rule, determining what studies it covers, and assessing whether there are any available alternatives. This will frequently mean we either can't make the most compelling arguments about the links between fossil fuel development and human health—or that, when we do make those arguments, our advocacy will have little to no effect on EPA decision-making. The process of adjusting our advocacy to account for these changes will consume our scarce resources.

9. And the EPA decision-making on which we depend will also suffer. When EPA refuses to accord full weight to the best available science reflecting the impacts of pollution and chemicals on human health—or must go through a more lengthy and difficult process in order to consider any such evidence—its standards and influential scientific information will be unable to fully account for the findings of that science. Even when it can do so, the lengthy review and exceptions process the Rule imposes mean that EPA decision-making will be slower and less responsive to scientific discoveries. This means fewer protections for Montana communities that depend on EPA regulation of pollutants and chemicals—including coal ash, carbon dioxide, benzene, particulate matter, and nitrogen oxides—and accordingly fewer of the protections CCE advocates for.

10. CCE members live and recreate on public lands and in urban spaces affected by pollution and chemicals attributable to coal mining, coal waste management, and oil and gas development. Concentrations of pollution and chemicals in these spaces create increased health risks for CCE members, including asthma, emergency room visits, and premature mortality. Damage from these pollutants to the landscape and the environment diminishes those members' enjoyment from recreating in affected spaces, including federal public lands. CCE members depend on EPA regulation to reflect the best available science to protect these spaces and the health of those who depend on them.

11. Because of these concerns, CCE intends to exercise its right to request that EPA administratively postpone the effective date of the Rule under Section 705 of the Administrative Procedure Act (APA). But, because of EPA's decision to issue the Rule effective immediately in violation of Section 553(d) of the APA, CCE is deprived of its ability to seek its desired stay.

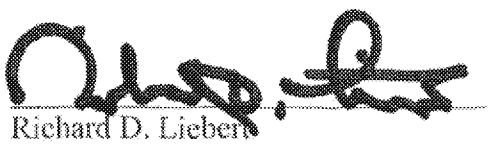
12. If the Court sets aside the EPA's decision to put the Rule into effect immediately, CCE will immediately join the other plaintiffs in this case in seeking a Section 705 stay.

13. If, however, the Court does not grant the requested relief, CCE will lose its right to seek such a stay and the Rule will remain in immediate effect—even if EPA otherwise would have postponed it. As a consequence, CCE and its members

will lose the opportunity to avoid the consequences of the Rule—including lost resources, disruption of science-informed regulation, and the health, safety, and welfare consequences that follow.

I declare under the penalty of perjury that the foregoing is true and correct to the best of my knowledge and belief.

Dated: January 8, 2021



Richard D. Lieben